World Health Organization

Medical equipment maintenance programme overview

WHO Medical device technical series

Medical equipment

maintenance programme

overview

WHO Medical device technical series

WHO MEDICAL DEVICE TECHNICAL SERIES:
TO ENSURE IMPROVED ACCESS, QUALITY
AND USE OF MEDICAL DEVICES

DEVELOPMENT

HUMAN RESOURCES

OF MEDICAL

FOR MEDICAL

DEVICE POLICIES,

DEVICES

STRATEGIES AND

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ACTION PLANS

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INTRODUCTION TO

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SAFE USE OF

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Decommissioning

MEDICAL EQUIPMENT

MAINTENANCE

MAINTENANCE

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Preface

Health technologies are essential for a functioning health system. Medical devices in particular, are crucial in the prevention, diagnosis, treatment and rehabilitation of illness and disease. Recognizing this important role of health technologies, the World Health Assembly adopted resolution WHA60.29 in May 2007. The resolution covers issues arising from the inappropriate deployment and use of health technologies, and the need to establish priorities in the selection and management of health technologies, specifically medical devices. By adopting this resolution, delegations from Member States acknowledged the importance of health technologies for achieving health-related development goals; urged expansion of expertise in the field of health technologies, in particular medical devices; and requested that the World Health Organization (WHO) take specific actions to support Member States.

One of WHO's strategic objectives is to "ensure improved access to quality and use of medical products and technologies." This objective, together with the World Health Assembly resolution, formed the basis for establishing the Global Initiative on Health Technologies (GIHT), with funding from the Bill & Melinda Gates Foundation. GIHT

aims to make core health technologies available at an affordable price, particularly to communities in resource-limited settings, to effectively control important health problems. It has two specific objectives:

• to challenge the international community to establish a framework for the development of national essential health technology programmes that will have a positive impact on the burden of disease and ensure effective use of resources;

• to chal enge the business and scientific communities to identify and adapt innovative technologies that can have a significant impact on public health.

To meet these objectives, WHO and partners have been working towards devising an agenda, an action plan, tools and guidelines to increase access to appropriate medical devices. This document is part of a series of reference documents being developed for use at the country level. The series will include the following subject areas:

• policy framework for health technology

• medical device regulations

• health technology assessment

• health technology management

› needs assessment of medical devices

› medical device procurement

› medical equipment donations

› medical equipment inventory management

› medical equipment maintenance

› computerized maintenance management systems

• medical device data

› medical device nomenclature

› medical devices by health-care setting

› medical devices by clinical procedures

• medical device innovation, research and development.

Medical equipment maintenance programme overview These documents are intended for use by biomedical engineers, health managers, donors, nongovernmental organizations and academic institutions involved in health technology at the district, national, regional or global levels. The purpose is to improve access to appropriate medical devices, and to improve their use and quality, in order to provide a better health-care system and thus enhance quality of life.

Maintenance series and external guidance

Three documents in this technical series have been developed specifical y to aid a health facility or a national ministry of health to establish or improve a medical equipment maintenance programme. The documents address medical equipment inventory management, maintenance, and computerized maintenance management systems.

Each of these documents can be used as a stand-alone document, but together they present al of the

factors to consider when developing a medical equipment maintenance programme. Furthermore, a six-volume comprehensive series of manuals for the management of healthcare technology, known as the 'How To Manage' series, exists for people who work for, or assist, health service provider organizations in developing countries and are publicly available.1

Methodology

The documents in this series were written by international experts in their respective fields, and reviewed by members of the Technical Advisory Group on Health Technology (TAGHT). The TAGHT was established in 2009 to provide a forum for both experienced professionals and country representatives to develop and implement the appropriate tools and documents to meet the objectives of the GIHT. The group has met on three occasions. The first meeting was held in Geneva in April 2009 to prioritize which tools and topics most required updating or developing. A second meeting was held in Rio de Janeiro in November 2009 to share progress on the health technology management tools under development since April 2009, to review the current challenges and strategies facing the pilot countries, and to hold an interactive session for the group to present proposals for new tools, based on information gathered from the earlier presentations and discussions. The last meeting was held in Cairo in June 2010 to finalize the documents and to help countries develop action plans for their implementation. In addition to these meetings, experts and advisers have collaborated through an online community to provide feedback on the development of the documents. The concepts were discussed further during the First Global Forum on Medical Devices in September 2010. Stakeholders from 106 countries made recommendations on how to implement the information covered in this series of documents at the country level.2

All meeting participants and people involved in the development of these documents were asked to complete a declaration of interest form.

1 Available at http://www.healthpartners-int.co.uk/our_expertise/how_to_manage_series.html
2 First WHO Global Forum on Medical Devices: context, outcomes, and future actions is available at: http://www.who.int/medical_devices/gfmd_report_final.pdf

Definitions

Recognizing that there are multiple interpretations for the terms listed below, they are defined as follows for the purposes of this technical series.

Health technology: The application of organized knowledge and skills in the form of devices, medicines, vaccines, procedures and systems developed to solve a health problem and improve quality of life.3 It is used interchangeably with health-care technology.

Medical device: An article, instrument, apparatus or machine that is used in the prevention, diagnosis or treatment of illness or disease, or for detecting, measuring, restoring, correcting or modifying the structure or function of the body for some health purpose. Typical y, the purpose of a medical device is not achieved by pharmacological, immunological or metabolic means.4

Medical equipment: Medical devices requiring calibration, maintenance, repair, user training, and decommissioning − activities usual y managed by clinical engineers.

Medical equipment is used for the specific purposes of diagnosis, treatment, or rehabilitation of disease or injury, and can be used either alone or in combination with any accessory, consumable or other medical equipment. Medical equipment excludes implantable, disposable or single-use medical devices.

3 World Health Assembly resolution WHA60.29, May 2007 (http://www.who.int/medical_devices/resolution_wha60_29-en1.pdf).

4 Global Harmonization Task Force (http://www.ghtf.org/documents/sg1/sg1n29r162005.pdf).

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Declarations of interests

Conflict of interest statements were collected from all contributors and reviewers to the document development. No conflicts of interest were declared.

Acronyms and abbreviations

AAMI

Association for Advancement of Medical Instrumentation **ACCE**

American College of Clinical Engineering

AHA

American Hospital Association

ASHE

American Society of Healthcare Engineering

BMET

biomedical equipment technician

CE

clinical engineering

CM

corrective maintenance

CMMS

computerized maintenance management system

EHT

Essential Health Technologies

FDA

Food and Drug Administration

GIHT

Global Initiative on Health Technologies

HT

Health Technologies

HTM

health/health-care technology management

IPM

inspection and preventive maintenance

ISO

independent service organization

META

Medical Equipment Technology Association

MRI

magnetic resonance imaging

PAHO

Pan American Health Organization

PM

preventive maintenance

PPE

personal protective equipment

UMTSN

Universal Medical Technology Service Nomenclature **UPS**

uninterruptable power supply

WHO

World Health Organization

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Medical equipment maintenance programme overview Executive summary

Medical devices are assets that directly affect human lives. They are considerable investments and in many cases have high maintenance costs. It is important, therefore, to have a well planned and managed maintenance programme that is able to keep the medical equipment in a health-care institution reliable, safe and available for use when it is needed for diagnostic procedures, therapy, treatments and monitoring of patients.

In addition, such a programme prolongs the useful life of the equipment and minimizes the cost of equipment ownership.

A maintenance strategy includes procedures for inspection, as well as preventive and corrective maintenance. Performance inspections ensure that equipment is operating correctly, safety inspections ensure the equipment is safe for both patients and operators, and preventive maintenance (PM) aims to extend the life of the equipment and reduce failure rates. Additional y, some hidden problems may be discovered during a scheduled inspection. However, performing inspections of equipment only ensures that the device is in good operating condition at the time of inspection and cannot eliminate the possibility of failure during future use; the nature of most electrical and mechanical components is that they can potentially fail at any time. Corrective maintenance (CM) restores the function of a failed device and allows it to be put back into service.

An effective medical equipment maintenance programme consists of adequate planning, management and implementation. Planning considers the financial, physical and human resources required to adequately implement the maintenance activities. Once the programme has been defined, financial, personnel and operational aspects are continual y examined and managed to ensure the programme continues uninterrupted and improves as necessary. Ultimately, proper implementation of the programme is key to ensuring optimal equipment functionality.

WHO Medical device technical series

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1 Introduction

Medical equipment maintenance can

and in conjunction with PM to ensure

be divided into two major categories:

functionality; this is important as PM can

inspection and preventive maintenance

be fairly invasive in that components are

(IPM), and corrective maintenance

removed, cleaned or replaced.

(CM) (see Figure 1). IPM includes

all scheduled activities that ensure

It is essential for any health-care facility,

equipment functionality and prevent

regardless of its size, to implement a

breakdowns or failures. Performance

maintenance programme for medical

and safety inspections are straightforward

equipment. The complexity of the

procedures that verify proper functionality

programme depends on the size and type

and safe use of a device. Preventive

of facility, its location, and the resources

maintenance (PM) refers to scheduled

required. However, the principles of a

activities performed to extend the life

good maintenance programme wil be the

of a device and prevent failure (i.e. by

same if it is in an urban area in a high-

calibration, part replacement, lubrication,

income country or a rural setting in a low-

cleaning, etc). Inspection can be

to middle-income country, for example.

conducted as a stand-alone activity

Figure 1. Components of a maintenance programme Maintenance

IPM Corrective .

maintenance

Inspection Preventive

maintenance

Medical equipment maintenance programme overview 2 Purpose

The objective of this document is to provide

The document is intended for those

information regarding the components

responsible for planning, managing

of an effective medical equipment

and implementing health technology

maintenance programme. It can assist

management services at the facility, local,

health-care organizations, especially

regional and national levels, particularly

those in developing countries, with

in resource-constrained countries where

planning, managing and implementing

such services may not yet be fully

the maintenance of medical equipment.

established. It may also be of value to

It is intended to be concise and flexible,

engineers and technicians responsible

and may be adapted to various settings

for carrying out the many tasks described.

and levels of technical resources as

required. It focuses on general principles

rather than being a rigid model, so that

each country or institution can design an

appropriate programme to meet their own

specific requirements.

3 Maintenance related definitions

Key terms used in the discussion of medical equipment maintenance are defined below.

Term	Definition
Acceptance testing	The initial inspection performed on a piece of medical equipment prior to it being put into service. When the device first arrives in the health-care facility, it is checked to ensure it matches the purchase order, it is functioning as specified, the training for users has been arranged and it is installed correctly. If a computerized maintenance management system (CMMS) is available, it is registered into the CMMS.
Calibration	Some medical equipment, particularly those with therapeutic energy output (e.g. defibrillators, electrosurgical units, physical therapy stimulators, etc.), needs to be calibrated periodically. This means that energy levels are to be measured and if there is a discrepancy from the indicated levels, adjustments must be made until the device functions within specifications. Devices that take measurements (e.g. electrocardiographs, laboratory equipment, patient scales, pulmonary function analyzers, etc.) also require periodic calibration to ensure accuracy compared to known

standards.

Clinical engineer

A professional who supports and advances patient care by applying engineering and managerial skills to health-care technology (American College of Clinical Engineering). While a clinical engineer is a specialized biomedical engineer, the terms are often used interchangeably.

Clinical engineering Engineer/technician or team of engineers/technicians responsible for the management and department/group

maintenance of medical equipment. Depending on the context and country, this department or team may be referred to by a wide variety of names. Some alternative names include: ‘biomedical engineering department’, ‘medical equipment maintenance department’, ‘medical equipment management unit’, etc. In this document, we refer most often to clinical engineering department.

Common descriptive The terminology used to describe a device. Using common universal descriptive names from a single nomenclature

internationally accepted source1 is key to comparing inspection procedures, inspection times, failure rates, service costs and other important maintenance management information from facility to facility.

Although manufacturers have specific names for devices, it is important to store the common name of the device as listed in the nomenclature system. (e.g. nomenclature name: electrosurgical system, monopolar/bipolar; vendor name for the device: electrosurgical generator; vendor model name: Radiolase).

Corrective

A process used to restore the physical integrity, safety and/or performance of a device after a Failure.

maintenance (CM)

Corrective maintenance and unscheduled maintenance are regarded as equivalent to the term repair.

This document uses these terms interchangeably.

Failure

The condition of not meeting intended performance or safety requirements, and/or a breach of physical integrity. A failure is corrected by repair and/or calibration.

Inspection

Inspection refers to scheduled activities necessary to ensure a piece of medical equipment is functioning correctly. It includes both performance inspections and safety inspections. These occur in conjunction with preventive maintenance, corrective maintenance, or calibration but can also be completed as a stand-alone activity scheduled at specific intervals.

Inspection and

IPM refers to all the scheduled activity necessary to ensure a piece of medical equipment is functioning preventive

correctly and is well maintained. IPM therefore includes inspection and preventive maintenance (PM).

maintenance (IPM)

1

Two common nomenclatures are the Global Medical Device Nomenclature (http://www.gmdnagency.com/) and the Universal Medical Device Nomenclature System (https://

www.ecri.org/Products/Pages/UMDNS.aspx)

 Performance

These activities are designed to test the operating status of a medical device. Tests compare the inspections

performance of the device to technical specifications established by the manufacturer in their maintenance or service manual. These inspections are not meant to extend the life of equipment, but merely to assess its current condition. Performance inspections are sometimes referred to as

‘performance assurance inspections’.

Predictive

This activity involves a forecasting technique to determine the rate of failure of certain types of maintenance

replaceable components (e.g. batteries, valves, pumps, seals). The maintenance interval is then set so components are replaced before they fail, ensuring the equipment continues to operate reliably. In health care this is primarily done in a facility that has a large number of medical devices from a single manufacturer or model.

Preventive

PM involves maintenance performed to extend the life of the device and prevent failure. PM is usually maintenance (PM)

scheduled at specific intervals and includes specific maintenance activities such as lubrication, cleaning (e.g. filters) or replacing parts that are expected to wear (e.g. bearings) or which have a finite life (e.g. tubing). The procedures and intervals are usually established by the manufacturer. In special cases the user may change the frequency to accommodate local environmental conditions. Preventive maintenance is sometimes referred to as ‘planned maintenance’ or ‘scheduled maintenance’. This document uses these terms interchangeably.

Repair

A process used to restore the physical integrity, safety, and/or performance of a device after a failure.

Used interchangeably with corrective maintenance.

Safety inspections

These are performed to ensure the device is electrically and mechanically safe. These inspections may also include checks for radiation safety or dangerous gas or chemical pollutants. When these inspections are done, the results are compared to country or regional standards as well as to manufacturer’s specifications. The frequency of safety inspections may be different to planned maintenance and performance inspections, and are usually based on regulatory requirements.

4 Maintenance programme planning

Planning a maintenance programme is

these extremes are infusion pumps,

part of a broader effort to establish a

defibril ators, ECG (electrocardiograph)

comprehensive programme for health-

machines, and hundreds of other types of

care technology management (HTM).

medical devices of various complexities.

This planning process includes a review

Early in the process of planning a

of critical factors, as shown in Figure 2.

maintenance programme, it is essential to

The challenge for planners is to balance

determine the types of devices that need

these factors to design a maintenance

to be included in the programme. This

programme that is appropriate and cost-

wil depend on the types of facilities to be

effective for their situation.

covered by the programme, ranging from

primary care clinics to tertiary hospitals,

and the range of devices in those facilities.

4.1 Inventory

The clinical engineering department

Medical devices range from relatively

should identify and select the devices to

simple to highly complex. For example,

be included in the inventory, and which

manual devices to measure blood

of those to include in the maintenance
programme. While some may prefer to
only few components and are easily
record all equipment in the inventory
repaired, assuming that parts, calibration
(and some government agencies may
instruments and basic hand tools are
require this), studies have shown that
available. At the other extreme are
not all equipment needs to be tracked in
advanced imaging and laboratory devices.
an inventory, inspected or maintained,
Repair of a magnetic resonance imaging
and very few hospitals or health-care
system requires extensive financial,
organizations have the manpower to
physical and human resources. Between
accomplish this level of effort. Approaches

Figure 2. Critical factors in planning a maintenance programme Critical factors

Inventory

Methodology

Resources

The types and numbers of
Identification of the method
The financial, physical, and
medical devices to be tracked
by which maintenance will be
human resources available to
by the hospital and those that
provided to the items included
the programme.
are specifically included in the
in the programme.
maintenance programme.

overview to selecting equipment to record in an
and manage the activities of these service
inventory and a maintenance programme
contractors. In practice, the typical
are important. Section 5.3.4 discusses
approach is to establish some level of
methods for prioritizing work, which are
management and technical capabilities
also helpful in the selection of equipment
within the health-care organization. Some
for inclusion in an inventory. Appendix
of the maintenance activities may also be
A.1 outlines one specific method in
conducted by employees of the health-
greater detail.
care organization. Other maintenance
activities may be conducted by service
The clinical engineering department
contractors or other external service
is responsible for developing and
providers. One of the most important
maintaining the inventory. They are

management activities is to decide which
responsible for routinely checking that
services should be provided by which
al the equipment being tracked within
combination of internal and external
a health-care facility is in the inventory service providers, , based on the capacity
and that all the equipment listed in the
of the facility and its staff. Further details
inventory can be located. The team may
on management and implementation are
find it convenient to perform an inventory
found in sections 5 and 6, which help in
while carrying out routine inspections or
designing an appropriate methodology for
PM activities. Furthermore, when new
a given context.
equipment arrives it should be inspected
and then added to the inventory.
Appendix A.2 outlines a policy for initial

4.3 Resources

testing and evaluation, while Appendix
D.1 provides a sample form for new
Resources needed for maintenance
equipment received. Please also refer
are difficult to project. This requires a
to *Introduction to Medical Equipment*
maintenance history, calculations of
Inventory Management in this technical
the staff requirement and knowledge of
series for further information.
when a piece of equipment might fail.
Maintenance also requires appropriate
staff skills, education and experience.

4.2 Methodology

Outside vendors are necessary for the
maintenance of complex equipment.
A maintenance programme can be
implemented in any number of ways so
Maintenance requires access to
it is important to consider the variety
equipment parts which may be difficult
of methodologies that are available.
to obtain due to budget limitations and
For example, it is possible for a health-
procurement difficulties, particularly
care organization to establish service
when purchasing from abroad. To prepare
contracts with device manufacturers,
for such challenges, it is important to
independent service organizations
consider in advance the financial,
(ISOs), or a combination of both. In such
physical and human resources necessary
cases it is essential for the health-care
to properly execute the intended activities.
organization to have personnel to monitor

4.3.1 Financial resources

in getting ready to do inspections, time
The financial resources required for
to obtain the equipment to be inspected
a maintenance programme (as one
(either bringing it to a central work area
component of a comprehensive HTM
or going to the location of the equipment),
programme) fal into two categories: initial
time to document the work done and
costs and operating costs. Initial costs are
re-order PM parts used, are all activities
investments that must be made before
that should be added to the total workload
the programme begins. Operating costs
calculation. An example can be found in
are ongoing expenses required to keep
Appendix C.
the programme in operation. Table 1
summarizes the major items within each
Direct maintenance costs can be difficult
category.
to estimate initially, but will improve with
time and experience. Service contract
costs, however, can be determined

Table 1. Financial resources required for a maintenance programme

	Initial costs	Operating costs
Physical	Space, tools,	Operation, utilities,
resources	test equipment,	maintenance,
	computer resources, calibration.	vehicles.
Human	Recruiting, initial	Salaries, benefits,
resources	training.	turnover, continuing
		education.
Direct	(not applicable)	Service contracts,
		maintenance
		parts and materials,

by negotiation with external service
providers. These types of services can
be acquired on a time and materials basis
or by contracting over a set period at a
fixed rate. In either case, the cost must
be planned in advance and included
in related budgets. Section 5.2.1
discusses further the issues surrounding
engagement of service vendors.
The cost of service ratio is a useful
measure in determining the financial
effectiveness of a maintenance

travel, shipping.

programme. This ratio is calculated by

dividing the total annual cost of operating

a medical equipment maintenance

The first step in calculating costs is to programme
by the value (initial cost)

specify the physical and human resources

of medical equipment in the inventory.

needed, based on the number and types

In the United States, for example, the

of medical equipment in the inventory,

cost of service ratio is between 5% and

and on the level and type of maintenance

10% (1). This ratio is achievable only

methodology selected. The initial and

when substantial supporting resources

operating costs are then calculated

are available, and only after an extended

using the applicable rates in the country

period of performance improvement.

or region. For the IPM component

For planning purposes in developing

specifically, it is helpful to estimate the countries,
this measure may be much

workload required by the programme.

higher, especial y for new programmes

This is a relatively straightforward process

in resource-constrained environments.

if the estimated time for inspections

However, the cost of service ratio, should

is known. By counting the number of

be monitored over time and be used as

devices of each type (each common

a guide for performance improvement

nomenclature type) and multiplying it

efforts.

by the estimated time, it is possible to

determine an estimated total workload for

Over time there will be opportunities

the IPM programme. Administrative time

to make additional investments in the

to create the IPM forms, preparation time

maintenance programme. For example,

overview the programme may consider providing

and medical gases, for example). It

service for a particular type of equipment

includes work benches and storage space

by using internal resources and staffing

for tools and test equipment, repair parts

rather than outsourcing the work. At each

and supplies, and equipment awaiting

such opportunity, a simple business plan

repair. It also includes space for records

should be drawn up that includes the

and documentation, service and operator

initial and operating costs of the proposal.

manuals, and access to whatever

Then the costs and benefits of the current

computer resources are required.

situation and the new proposal can be
compared. This decision-making process
Inclusion of computer resources in
for new investments is particularly
the workspace is also important to
effective when it is informed by actual
consider. Basic documentation may
data from the programme.
be maintained with paper records but
the use of a computer spreadsheet,

4.3.2 Physical resources

database programme, or computerized
A maintenance programme relies on a
maintenance management system
number of physical resources. These
(CMMS) supports good record-keeping,
include the workspace, tools and test
performance monitoring and performance
equipment, supplies, replacement parts,
improvement (see section 5.3.6 for more
and operation and service manuals
information). Additionally, when internet
needed to perform maintenance. When
access is available, it can be a valuable
planning a maintenance programme each
resource. Many technical resources are
of these should be considered individual y
available online at little or no cost, and as follows.
online educational programmes may be
an option to further technical knowledge

Workspace

and facilitate training.1 Furthermore,
The location in which maintenance will
inexpensive voice communication and
take place should be considered when
e-mail communication enable effective
planning the programme. One option is in
collaboration across wide distances.
the location where the equipment usual y
However, where internet communication
resides. For some types of equipment
is unreliable, keeping in touch by mobile
such as X-ray systems, laboratory
phone can be an effective alternative.
analyzers, sterilizers, and surgical lights,
going to the equipment is the only option.
The clinical engineering workshop is
In this case, planning to take essential
typical y found within the facility itself, tools and test equipment to the work
but if the programme includes multiple
site or equipping a space closer to the
facilities it may be more economical to
equipment is necessary.
establish a centralized repair depot.
The second option is to transport the

Tools and test equipment

equipment to the clinical engineering
The productivity of biomedical equipment
department’s repair shop to have the

technicians (BMETs) will be limited

IPM or CM performed. This may be a

without appropriate tools and test

time consuming process, but the clinical

equipment. As purchases are planned,

engineering department may be the

it should be noted that investment in

only location where some maintenance

tools and test equipment results in

can be performed. A good workspace

is clean and well-organized. It provides

1 An example of an online educational opportunity is the series of courses developed good lighting and access to utility systems

by the University of Vermont in USA (http://its.uvm.edu/medtech/index.html).

Spanish language versions of the courses are offered through Universidad CES

required by the equipment (electricity

(Colombia) and Pontifica Universidad Católica de Peru.

reduced maintenance costs. In addition,

imaging technology changes so quickly.

having the right equipment wil greatly

Tools and, in particular, test equipment

increase the reliability of the readings,

must themselves be appropriately

the accuracy of the calibrations, and the

maintained. They should be kept in

margin of safety for the patients and staff,

good physical condition, calibrated at

as well as the efficiency of the staff doing

appropriate intervals, and repaired as

the maintenance.

required.

Various tools and test equipment are

Where resources are constrained,

required to perform IPM and/or CM

creativity is required; establishing a

procedures, depending on the type of

network of technicians and engineers

equipment in service. It is possible to

may mean that tools can be shared.

perform a large proportion of IPM and

Facilities with few financial resources

CM procedures satisfactorily with a basic

can consider renting or sharing expensive

set of electronic service tools and test

test equipment and tools with other

equipment (e.g. temperature meter,

hospitals in the surrounding area. *Medical*

volt meter, force gauge, oscilloscope,

instrumentation in the developing world

resistance and capacitance substitution

recommends a minimum set of tools and

boxes, an electrical safety meter).

test equipment for low-resource settings

Small hospitals or clinics with a limited

(2). These recommendations represent

amount of medical equipment can

the most basic level of investment in
run their programme with just several
tools and test equipment that can enable
pieces of basic test equipment (e.g. a
meaningful service for medical devices.
physiological simulator, safety analyzer
and some basic tools). In larger facilities
Initial funding to start a programme
with more complex equipment, more
is necessary, but so too is providing
advanced tools and test equipment may
additional ongoing funding to purchase,
be necessary. For example, in a large
calibrate and service test equipment for
hospital with more than a few operating
new medical equipment the hospital
rooms and modern electrosurgery
may acquire in the future, or for test
equipment, an electrosurgical analyzer
equipment needed to expand the scope
may be a prudent purchase. Purchasing
of the maintenance programme.
more advanced tools and test equipment
will enable clinical engineering technical
A detailed list of test equipment and the
staff to calibrate, maintain and repair a
devices they are required for is provided
wider variety of medical equipment. If it
in Appendix F.
is not possible to procure and maintain
certain test equipment, it may not be

Supplies

appropriate to take responsibility for the
These primarily consist of cleaning and
maintenance of the associated device.
lubricating supplies, and need to be
acquired in sufficient quantities. The
The life of tools and test equipment may
manufacturers' service manuals give
exceed ten years if they are carefully
cautions about using the wrong cleaning
maintained. Typical y, test equipment can
agents, which can damage labelling and
be used for about seven years. Highly
the plastic surfaces of some equipment.
specialized items, such as troubleshooting
software and laptop computers to connect

Replacement parts

to computer-based laboratory or imaging
When planning an IPM programme, it
equipment, may have a shorter useful
is possible to forecast in advance what
lifespan because the laboratory and
parts need to be replaced and how

Unfortunately, operation manuals and
guidelines. Thus, based on the number
service manuals are not always available,

of devices at the facility, the replacement
or may be in a language not spoken by
parts (or parts kits) to be used during
equipment technicians. Therefore, it
preventive maintenance (e.g. batteries,
is important that a clinical engineering
filters, valves, tubing, seals, etc.) can
department take steps that al ow them
be ordered many months in advance,
access to such manuals. For existing
optimizing any volume discounts and
equipment, the manuals may be borrowed
minimizing shipping costs. Most
from other local hospitals or obtained
importantly, the replacement parts wil be
online. Clinical engineering department
on hand when needed. This practice will
managers should, if possible, have
improve reliability and availability of the
access to high-speed Internet service for
equipment and increase the productivity
this purpose. Manuals or advice may be
of the staff performing the maintenance.
found among the wider health technology
management community, such as the
In many countries the problem of obtaining
Infratech mailing list.2
replacement parts at a reasonable cost
and in a timely manner can be substantial.
For new equipment, it is important that
However, knowing what will be needed
these manuals are included as part of the
and the associated costs will help in
purchase agreement. All manufacturers
planning maintenance and informing
who sell equipment are required to
management in advance. This may lead
provide detailed IPM procedures for use
to funds being redirected to critical areas.
by those who buy their equipment. These
The use of generic parts instead of the
procedures are usual y written very clearly
manufacturer’s parts is an option if the
and in many cases with illustrations for
quality and characteristics of each part
performing complete and appropriate
is careful y analyzed. Purchasing generic
IPM. Manufacturers may not provide
parts from specialty medical equipment
specific IPM procedures, maintenance
parts suppliers – who do the engineering
and service manuals, troubleshooting
analysis and guarantee the parts they
guidelines, parts lists and schematics
sel – is a reasonable solution in many
unless the owner requires them to do
cases, but associated risks (e.g. loss of
so at the time of purchase. Even if
manufacturer guarantee, non-compliance
the hospital staff does not plan to do

with equipment specifications that leads
maintenance on a particular piece of
to device failure) must be carefully
equipment, having maintenance and
considered beforehand.
service manuals enables the hospital
to provide the manuals to external
Operation and service manuals
maintenance providers or do the repairs
Ideally, the maintenance programme will
themselves in the future if circumstances
have an operation (user) manual and a
change.
service manual for each model of medical
equipment. The operation manual is
For donated equipment, when manuals
valuable not only for equipment users
have not been provided and due to the
but also for equipment technicians who
age or type of equipment are impossible
need to understand in detail how the
to access, the instincts and know-how
equipment is used in clinical practice.
of the staff will be the primary resource.
The service manual is essential for
However, the clinical engineering
inspection, preventive maintenance,
repair, and calibration.

2 Instructions on how to join the Infratech listserv are found here ht p://
infratechonline.net/?page_id=38

department should consider developing
clinical engineers come into the position
their own guidelines and emphasizing
after completion of a four to five year
the importance of including operation
bachelor's degree progamme, while
and service manuals with every donation.
biomedical equipment technicians often
Developing countries should work with
come into the position with two year's
responsible donor agencies and insist
post-graduate training and a degree or
on adherence to appropriate guidelines.
certificate in biomedical electronics or
Please refer to *d* in this technical series biomedical equipment technology.
for more information.
Alternatively, particularly in countries with
In all cases, it is important to discuss
fewer specialized training programmes,
with the supplier if manuals are available,
engineers and technicians may be trained
or can be made available, in the local
in a related field (such as industrial
language, perhaps at an additional cost.
engineering or electrical technology) and
have taken certificate courses, received

4.3.3 Human resources

training or completed an apprenticeship
Developing the human resources
enabling them to work in the area of
necessary to operate an effective
medical equipment. Engineers or
maintenance programme is a slow and
technicians must have this additional
steady process. The first step is to identify
training because medical equipment
the number and type staff that a facility
is highly specialized and if improperly
(or group of facilities) requires. For
maintained or repaired may have adverse
example, a small health-care facility may
consequences on human life. This type
have a single technician who provides
of engineer or technician is usual y easier
services for a small inventory of relatively
to find in the employment marketplace,
simple equipment. On the other hand, a
but will need more supervision and
clinical engineering department serving
training to effectively accomplish their
a large number of health-care facilities,
work. Overtime and with experience,
especial y when those facilities include
technicians may become qualified to take
higher level hospitals, wil have a large
a position as a biomedical equipment
number of technical and management
technician. However, for engineers to
personnel, including specialists in
become qualified as a biomedical or
particular technologies, with multiple
clinical engineer, they must receive the
levels of supervision. In general, however,
relevant higher education and degree.
there are two categories of clinical
Table 2 provides a classification of the
engineering personnel: technical and
types of technical personnel and their
management.
typical duties.

Technical Personnel

In many countries there is a shortage of
Within the category of technical personnel
qualified clinical engineers and biomedical
are engineers and technicians. Biomedical
equipment technicians. A long-term
or clinical engineers, are educated in
solution is to develop the educational
general engineering principles, the
infrastructure so that qualified technical
physical and biological sciences and
personnel can be created within the
their application to medical technology.
country or region. It may be a good idea
Similarly, technicians receive technical
to include universities within the country
training with a primary focus on medical

or region in human resource planning

equipment maintenance. Biomedical or

as they can develop formal degree

24

Medical equipment maintenance programme overview **Table 2. Classification and roles of technical personnel** Personnel

Title

Role

Engineer

Biomedical engineer or clinical engineer

Management, specialized maintenance, supervision of external service provider, needs assessment,

planning, and user training.

Other related fields

Require a training course and certificates to work (e.g. electrical engineer, mechanical engineer)

in the medical device field. Primary focus is on the maintenance of medical equipment and sometimes

managerial positions.

Technician

Biomedical equipment technicians

Primary focus on specialized medical equipment

repair and maintenance.

Other related fields (e.g. electrical or medical Preventive maintenance and repair of less complex technologist, polyvalent technician)

equipment. It is important that they receive

specialized training for high-risk medical devices.

Service provider

Engineer or technician

Provide maintenance that cannot be performed in

house. They are product-oriented and specialized in a certain field.

programmes and provide continuing

and CM for equipment that internal staff

education for technical personnel. In

are not able to complete. Furthermore,

the short-term it is necessary to recruit

repair work on the most sophisticated

engineers and technicians from other

medical equipment is only accomplished

disciplines, as outlined above, and to

by highly trained specialists who focus

provide them with training related to

on a single technology or small group

medical technology.3

of technologies. These outside vendors

should operate under the supervision

The size of a health-care organization, the

of in-house biomedical equipment

number and type of medical equipment

technicians for the purpose of service

in the maintenance programme, the skil s

management, cost control and the

found in the local marketplace, and the

opportunity to become increasingly

financial capacity of the organization will

familiar with other equipment.

be the basis for identifying the correct

blend of engineers and technicians.

Having some lower level general staff

Almost all maintenance programmes

to undertake less technical work is

will find it necessary to complement

acceptable, but most of the maintenance

the internal staff with external

staff wil need to have electronics training

service providers (either the vendor/

and an understanding of the functioning

manufacturer's service representatives

of test equipment, concepts of electronic

or third-party service representatives).

calibrations and the operating principles

Such providers may perform the IPM

of the medical equipment in order to do

the job effectively. In addition, investing

3 In addition to numerous workshops conducted by the World Health Organization in higher level technicians may allow

(WHO) in Nepal and the Russian Federation, as wel as in various African the clinical engineering department to

and Baltic nations, etc., the Pan-American Health organization has conducted numerous workshops on CE and HTM in countries throughout Latin America and eventual y provide in-house service on

the Caribbean, in cooperation with ACCE (www.accenet.org). Engineering World Health (www.ewh.org) also conducts technical training programmes in Costa Rica even the highest level laboratory, surgical

and Kenya. ORBIS International conducts similar programmes in Bangladesh, and imaging equipment. In general, the

China, Ethiopia, India, Peru and Viet Nam.

more the work that can be undertaken by

p r o g r a m m e . I n c o n c e r t w i t h in-house technical staff helps to limit the

hospital administration, they set

overall cost of maintaining the hospital's

department policies, provide budget

medical equipment. Hiring wel trained

recommendations, supervise technical

and qualified biomedical equipment

staff, arrange for training, set priorities for

technicians, who can assume more

the department activities and administer

responsibility, will reduce the cost of

the overall programme. The background

maintaining a hospital's equipment.

of those in this position may include a

technical degree (two years) with many

Where substantial resources are available

years of experience in medical equipment

to support technical personnel, it is

service, but a preferable combination

typical that one technical person may

would be someone with a four-year

be responsible for the maintenance

engineering degree and familiarity

of several hundred medical devices.

with the health-care environment and

However, in countries without such

health-care technology. Management

support resources, the number of devices

personnel can also have a combination
per technical person must be greatly
of business and technical training. They
reduced. This is especial y true in the
may be engineers or technicians who
early stages of implementing a health
have additional training and experience
technology management programme.
in management and supervision. The
Over time, performance improvement
number of management personnel
efforts will increase the productivity of
required in a clinical engineering group
individual personnel. Care should be
depends on the size and structure of
taken, however, to avoid overburdening
the group and is based primarily on
technical personnel at the outset of new
maintaining an appropriate ‘span of
programmes.
control’ for each supervisor and manager.

Management Personnel

Sample job descriptions for the
Engineering management staff provide
positions outlined above are provided in
leadership for the maintenance
Appendix G.

Once established, it is essential to
This information may be used to calculate
manage the programme in an effective
the cost of service ratio described in
and economical manner. Programme
section 4.3.1.
management has several aspects that
are typically addressed concurrently, as
Managing the maintenance budget is not
seen in Figure 3.
unlike managing any other organizational
budget. The established budget

Figure 3. Management aspects of a maintenance programme

represents the target or benchmark
for the programme. Actual costs are
compared to the budget. Any difference
Financial
between actual and budget data triggers
management
a review of the reasons for the variance.
Budgeting can be problematic with
regard to CM costs because such costs
Personnel
Operational
are unpredictable. An unexpected and
management
management
expensive repair required for a critical
medical device can cause a substantial
budget variance. However, expenses of

this type must be anticipated as much as possible so that, over time, the average level of CM expenses remains within the target budget. It is a good idea to allocate the cost of repair to a separate account from the IPM work. This will al ow for accurate cost accounting and future budgeting for IPM and more accurate repair accounting. Additionally, it is important to consider adjusting the maintenance budget after acquisition of new equipment or removal of existing equipment as this affects costs associated with both IPM and CM.

5.1 Financial management

Financial management for a maintenance programme focuses primarily on two tasks: *monitoring costs and managing the budget.*

Costs are monitored by accurately documenting al of the time and expenses associated with maintenance activities. For work performed by technical personnel, this is typically accomplished by recording this information on a work order document, fol owed by entry into the CMMS, if available. Specifically for work performed by external service providers, the contract costs (or the itemized costs for service) are recorded on the work order, or into the CMMS. The result is that there is a history of al time and expenses associated with maintaining that device.

5.2 Personnel management

The purpose of personnel management is to provide support to the maintenance programme's human resources so that programme objectives are achieved. Work assignments should be made to match the skills of the technical personnel and to promote efficiency. Typical y, technical personnel wil be assigned a combination of IPM and CM responsibilities. However, there may be cases where emphasis on one or the other types of maintenance activities is appropriate. Section 5.3.3 specifical y discusses the various aspects of scheduling maintenance activities.

Performance

Performance

improvement

monitoring

Financial management for a maintenance programme focuses primarily on two tasks: *monitoring costs and managing the budget.*

Costs are monitored by accurately documenting al of the time and expenses associated with maintenance activities. For work performed by technical personnel, this is typically accomplished by recording this information on a work order document, fol owed by entry into the CMMS, if available. Specifically for work performed by external service providers, the contract costs (or the itemized costs for service) are recorded on the work order, or into the CMMS. The result is that there is a history of al time and expenses associated with maintaining that device.

Independent service organizations range in size; some specialize in a particular equipment from other manufacturers, in some cases extending to all the medical equipment in a health-care organization.

Personnel management also includes
type of medical equipment and others
monitoring service vendors when
offer maintenance services for a wide
maintenance must be outsourced (see
variety of equipment types.
5.2.1 below). It is important to monitor the
productivity of internal and outsourced
In some parts of the world there are many
technical personnel on a regular basis.
external service providers, which offer the
When applied to individual in-house
clinical engineering department manager
technicians, productivity monitoring
a wide variety of options. However, in
can identify those technicians needing
other parts of the world the number of
additional support or training. When
external service providers is much more
applied to the maintenance programme
limited. In some cases these companies
as a whole, productivity monitoring can
find it uneconomical to offer services
identify opportunities to improve the cost-
in remote areas with small inventories
effectiveness of the programme. More
of equipment. They are more likely to
details on performance monitoring and
expand their service areas if it possible
improvement are found in sections 5.4
to negotiate a contract that covers a
and 5.5.
large inventory of equipment, especially
if that inventory has a reasonable level of
The most important aspect of personnel
standardization in terms of manufacturer
management is the ability to ensure
and model. In some cases, it may be
adequate training. Training on new
reasonable to consider liaising with other
equipment, as well as routine refresher
health-care facilities in order to provide
training on existing hardware, is necessary
better justification for the external service
to ensure that technical staff are capable
providers to enter the local market.
of properly maintaining and repairing the
medical equipment included within the
There are several types of service
scope of the programme. Section 5.2.2
agreements as outlined in Table 3. Service
discusses training in further detail.
agreements can include various levels of
scheduled maintenance, unscheduled

5.2.1 Service vendors

maintenance, or a combination of the
As mentioned, it is often not possible
two. Flexibility in the terms of service
to provide al maintenance services in-
agreements is valuable to the clinical

house. In such circumstances, it may be
engineering department manager, but
necessary to make use of external service
care must be taken to fully understand
providers for a significant portion of the
those terms before entering into a formal
maintenance activities.
agreement. Additionally it is advisable
to check the references of any outside
There are generally two categories of
vendor prior to hiring them.
external service providers: *equipment*
manufacturers and independent
After a service agreement is in place, it is
service organizations. Many equipment essential to monitor the performance of
manufacturers offer scheduled and
the service provider. This is necessary to
unscheduled maintenance services
make sure that the terms of the agreement
for the equipment they manufacture.
are being met and that the health-care
Some also offer maintenance services for
organization is receiving the services it

Table 3. Service agreement types

inside the organization. This may
be a clinician teaching biomedical

Type	Description	Rates (cost)
Full service	Quick response available at all times	Fixed
	technician who is familiar with	Time and
	Varying response time	Hourly charge
	material	plus cost of
	available as needed	maintenance and operation.
service	parts	
• The biomedical equipment technician taking part in a education	Shared	Internal staff provides
responsibility initial response and repair.		
class for nurses or other clinical	External staff follows up as	
users to learn about the operation of	and when required.	
the equipment.		
• The clinical engineering department		
needs. All maintenance activities and		
bringing in a specialized outside		
associated costs they perform should also		

trainer to teach staff about
be recorded (i.e. in a CMMS, if available)
maintenance of a particular piece or
and reviewed on a regular basis.
type of equipment.
• The clinical engineering department

5.2.2 Training

bringing in one of the manufacturer's
For the safety of the patient and the user,
trainers to present to biomedical
proper training is critical for both the user
equipment technicians about
and the technical staff. The technical staff
maintenance and operation.
and the clinical engineering department
manager have dual responsibility for
Or training can take place outside the
ensuring that the technical personnel as
organization at:
well as the clinical users are informed,
• Third-party training programmes
trained and versed on their specific
designed to explain several models
responsibilities. Training and education
of a specific technology.
is not a one-time activity but a continual
• Manufacturer's training programmes
process. Enabling staff to see that
specifically designed for equipment
learning is important and a constant
technicians.
feature of their job will improve reliability
and success in future problem solving.
The methods of training suggested
This section describes the training of
above, progress from the least expensive
technical personnel and section 5.3.9
to the most expensive to implement.
briefly discusses user training.
So depending on hospital resources,
local availability of information sources
Training of technical personnel can
and the ability to coordinate with other
be provided inside the health-care
hospitals who might have technicians
organization through:
to train as well, the hospital can choose
• Self-study:
a methodology that best matches their
› reading the equipment service and
resources. It should be noted however
training manuals;
that the most effective training methods
› using additional self-study
for sophisticated equipment are the more
materials provided by the
expensive otpions.
manufacturer;
› using materials provided by a third
The most sophisticated equipment in

party.
hospital settings consists of computer-
• One-to-one training provided by
based multi-component systems.
a more experienced person from
Most of the performance inspection

and verification of this equipment is
• Provide recommended forms to be
performed by software-based inspection
used for the IPM procedure.
systems built into the equipment itself.
• Be provided in the predominant
Obtaining access to the computer codes
major language of the region/country.
and understanding how to maintain this
If this is not possible, the department
equipment may only come with training
will then have to consider if this is
provided by the manufacturer or vendor
the best purchase for them or if they
for a fee. If the hospital has developed a
can afford to translate the manuals
competent staff of biomedical equipment
themselves.
technicians, service training by the vendor
is a good investment as it enables the
Procedures should not be changed until
hospital to eliminate vendor-related costs
the owner has some experience with
and may also lead to the hospital being
the device. Then, based on inputs from
able to assume repair responsibilities.
biomedical equipment technicians and/
or other organizations who also own the
equipment (or industry recommendations),

5.3 Operational management

IPM procedures can be changed. If this
is done, the justification for deviating

5.3.1 Developing or changing IPM

from the manufacturer's suggested

procedures

IPM procedure should be thoroughly
For IPM to be conducted properly,
documented for future reference. The
procedures are either selected or
decision to make this change should also
written so they provide sufficient testing
be reviewed periodical y (e.g. annual y) to
and maintenance for specific devices
make sure the conditions leading to the
and their features. The process of
change persist.
selecting or writing must begin with a
good understanding of the technology
In most cases, the unique characteristics
in general, and the relevant model of
and features of devices require unique
equipment.

inspection steps for each different
model. However, in some cases, a
When developing new procedures for
generic procedure for al manufacturers
either old or new equipment, it is best to
and models (e.g. oto/ophthalmoscope,
take the most conservative approach and
fibre optic light source, microscope) can
use the manufacturer's IPM procedure
be used. While using available generic
manual as a baseline. The equipment
procedures may be very convenient, it
owner should expect IPM procedures
must be done with understanding and
from the manufacturer to:
discernment as some are written with
• Be well designed and easy to
the intention of providing only the most
understand.
basic steps in an inspection. In addition,
• Clearly explain every step in the
Appendix B contains a procedure template
procedure.
and a few sample generic procedures.
• Explain what test equipment is
required.

5.3.2 Setting IPM frequency

• Explain what the upper and lower
The frequency of IPM is specified by
limits for measurements the
the manufacturer of the equipment in
biomedical equipment technician
the maintenance manual. In cases
will take.
where there is sufficient familiarity with
• Show how to replace parts.
the equipment or because of resource
• Explain the required frequency of
constraints, the clinical engineering
specific steps.
department manager may prefer to modify

overview what equipment to inspect, how often
the clinical engineering department is
maintenance should be performed and
important. See section 5.3.8 for more
what parts should be replaced. Before
on effective communication. Because
changing the inspection frequency of
they are unscheduled, CM activities
a medical device, he manager should
will increase or decrease with demand.
consider the regulatory environment, the
Therefore it is important to have a
physical environment, the level of user
prioritization scheme in place so that CM
training, the reliability of the equipment,
resources are directed toward the most
the frequency of use, how much wear the

critical needs (see section 5.3.4 for more
equipment receives during normal use,
information on prioritization).
and the number and types of technical
staff available. This information could
For IPM, the workload is best scheduled
then be presented to a multidisciplinary
over the calendar year so that the
safety committee (if available) or
work schedule and staff capacity can
hospital management, to make the final
be aligned. However, during vacation
decision. In this way, the decision-making
or holiday periods where staffing levels
responsibility is spread to a broader group
in the department may be reduced,
of interested parties. When the clinical
consideration can be given to reduce the
engineering department is unfamiliar with
IPM workload by moving IPM inspections
the equipment, it is best to simply fol ow
to another time. Measuring the workload
the manufacturer's recommendations and
created by scheduled IPM helps identify
adjust the procedures and frequency only
where adjustments may be needed.
after familiarity increases. Where a level
Appendix C explains how the IPM
less than the manufacturer's specification
workload can be calculated and related
is determined, this should be noted in the
to staff time so they can be matched as
equipment's maintenance record.
closely as possible.

5.3.3 Scheduling maintenance

Work can be assigned manually by
Efficient use of technician time wil reduce
management personnel or automatically
down-time of equipment and minimize
by the CMMS, using rules established
overall expenses. The most appropriate
by management. Greater efficiency can
method for scheduling maintenance in a
be gained by creating a system where
particular health-care facility should be
IPM technicians can focus on the work
chosen. For inspections, one approach is
at hand without interruption. This will
to plan for the equipment in a given clinical
require sufficient staff to be able to
department to be inspected at the same
handle repairs or service calls that may
time. This works very well for equipment
be unrelated to IPM work.
that does not move from the department.
Another approach would be to schedule

5.3.4 Prioritization of work

inspection of equipment of a given type
Continuous matches between workload
(e.g. defibrillators) simultaneously. For

for the equipment in the hospital and

preventive maintenance, equipment

the staff available to do the work are

may be scheduled by calendar dates

rare. So, rather than plan a programme

depending on the manufacturer's

with the goal to inspect and maintain all

recommendation (e.g. once every 3

the equipment and then not completing

months etc.). Alternatively, it can be

the scheduled work, (thus leaving some

scheduled by hours of usage (e.g. for

of the critical, high risk or life support volume
ventilators). In this case, creating

equipment not serviced), it is better

a method for the users to communicate

to carefully identify the equipment in

the device's elapsed usage time to

the health-care facility that is the most

important to inspect and maintain, and

patient if they do not function properly

schedule this work as a priority. Creating

and have a significant potential to function

such a 'tiered process' , where the most

improperly if they are not provided with an

important equipment is dealt with first,

adequate level of IPM. Devices excluded

is a better use of limited resources.

are those for which there is no evidence

When additional staff is added and their

that they benefit from scheduled IPM.

training completed, the next lower tier of

equipment can be added to the schedule.

Resource-based prioritization

Managing the process in this manner

This methodology uses any of the

gives the manager more control over both

three prioritization models (see above),

the work and the outcome. The following

in combination with knowledge about

are examples of how maintenance may

the staffing and resource levels of the

be prioritized.

particular facility or region, in order to define
maintenance priorities. In this

Risk-based prioritization

way, the devices with the highest risk,

One method used to prioritize medical

most important to the work of the hospital

equipment IPM is based on assigning

or that are maintenance critical would

the highest priority to equipment with

be maintained first, and other devices

the highest likelihood of causing patient

with a lower prioritization rank would be

injury if it fails. Categorizing devices by maintained
if resources permitted.

maintenance priority, and identifying

those that are of such a low risk that

In addition to these methods, priority may
maintenance is not necessary, requires
be given to IPM and CM of equipment
a systematic approach. For over 20
that generates revenue for the health-
years the Joint Commission for the
care organization. The same is true
Accreditation of Healthcare Organizations
when the non-availability of equipment
has required a risk-based approach to
incurs higher costs for the organization
prioritizing IPM of medical equipment
(due to the costs of temporary rental of
(3). An example of how this risk-based
replacement equipment, for example).
technique is implemented is shown in
Appendix A.1.

5.3.5 Keeping records

The record for each device should
Mission-based prioritization (4)
include identifying data such as a brief
This methodology is based on the
description, manufacturer, model, serial
question: Which devices are most
number, and location (see *Introduction*
important to us in providing the majority
to Medical Equipment Inventory
of our patient care? For example, if the
Management in this technical series for
hospital's priorities were caring for people
more details). It is helpful to also include
living with HIV and caring for pregnant
data regarding the time and expense of
women and their children, the equipment
providing scheduled and unscheduled
used in this type of care would become
maintenance services for the device.
the priority. The second priority after
These data are typical y contained in work
this work is completed would then be
order records that provide documentation
those devices with the highest risk (as
of every maintenance task performed
described by the method listed in the
on the device. As a result, the inventory
previous section).
database will contain the entire technical
and financial history for each device in
Maintenance-based prioritization (5)
the inventory. Appendix A.4 provides a
This methodology analyzes which devices
sample policy outlining how to manage
have a significant potential to harm a
a work order system for corrective

overview maintenance and Appendix D.3 provides
computer system. Thus, a computerized
an example of an actual work order form.
maintenance management system

(CMMS), a software tool that is able to
From a regulatory point of view, work that
run on a stand-alone computer, can be
was not documented is work that was
a very useful in managing the medical
never performed. Additionally, when a
equipment maintenance programme.
problem with a piece of equipment occurs,
it is helpful to see what previous work was
In an effort to effectively manage a good
done and what the measurement values
programme, a CMMS system may provide
were. Therefore, it is invaluable to have
the following capabilities:
thorough documentation of all service
• Keep an inventory of each device in
events which have taken place over the
the facility, including the ability to
life of the equipment. Being able to keep
easily add or change the equipment
this in a CMMS for electronic retrieval is
information.
ideal, but simply having the information
• Keep track of past service events
available in a paper format is still useful.
(e.g. IPM, CM, recalls, software
updates etc.) and retrieve or print
The maintenance programme must strive
them if needed.
for accurate records of both the total list of
• Store IPM procedures and related
equipment requiring maintenance as well
information.
as an accurate accounting of the specific
• Schedule IPM procedures, change
work completed. Using an organized
the schedule of IPM procedures and
CMMS system to print appropriate
print a summary list of what has been
procedures for each scheduled activity,
scheduled.
and a good system of annotations and
• Print individual IPM forms with the
coding to record the results of the IPM
appropriate procedure, the past few
(for quality control and productivity
service events (for reference), and
analysis purposes), are good methods to
the expected IPM completion date/
keep records. Another important aspect
time.
of equipment control and tracking is
• Record and store the results of
keeping accurate records of locations of
the IPM inspection procedures
equipment to facilitate quick location of
– including tasks that passed or
equipment for procedures. If attention is
failed, the measurements taken and
given to keeping accurate records and

the acceptable range of measured values.

• Record the CM activity including the problem with the device, time spent in the repair process, a description of the work done and the list of parts used.

• Produce summary reports of:

› IPM completion rates;

› IPM that failed and required repair work;

› IPM actual versus expected completion times;

› Inventory lists of equipment by location, owner or device type;

› Repairs completed in a certain time period;

› List of parts used to repair equipment over a certain time period.

• To identify to IPM technicians which devices have been completed and which are still due for IPM.

When taking power measurements on a dual system. The initial inventory is taken on computer but also on paper, so that there is a back-up option, and staff can be confident that there is a form of record keeping available with which they feel comfortable. The active development of an inventory may also function as an

information, many hours can be saved in trying to locate equipment that was recently removed from service, disposed of, put in storage or was moved to a different department. Keeping database information updated is an ongoing task, which is wel worth the effort when striving for good programme management.

5.3.6 Computerized maintenance management systems

In most modern health-care facilities, the number of pieces of medical equipment and the number of service events are so large that keeping and organizing this information can only be done by a

shortage of staff, and particularly of adequately trained staff, the process of implementing a CMMS may begin as

inspection form but many hospitals also choose to record these readings on a sticker which is placed on the equipment for future reference. See Appendix D.2 and Appendix E for examples of

extended training period. Once the initial

inspection forms and labels.

inventory is established, and staff are

more comfortable with computers and

Some hospitals use coloured inspection

with the inventory system, the paper

stickers to indicate when the device was

records can be phased out.

last inspected in (e.g. yellow – this year,

blue – last year, pink – two years ago,

Computerized maintenance management

etc). This helps readily identify which

system in this technical series is a good equipment
is next due for inspection.

resource when ready to implement such

a system, as it provides details on the key

5.3.8 Communication

elements of an effective CMMS. In cases

Keeping in mind that the ultimate

where a CMMS may not be possible

objective of a maintenance programme

or is not necessary (e.g. health centre,

is to improve patient care, it is essential to

small hospital), *Introduction to medical*

develop strong working relationships with

equipment inventory management in

clinicians and to understand their needs.

this technical series is a good resource

The user will know what to expect from

on getting started with tracking current

the clinical engineering department and

inventory and equipment maintenance

vice versa. Respect is shown to the user

in a paper-based way.

for their role in helping to complete the

maintenance, resulting in appreciation for

5.3.7 Tags and labels

the work and responsibilities of the clinical

It is good practice to label each piece

engineering unit. Furthermore, having an

of medical equipment with a unique

effective dispatch communication system

identification number. This number will

in place will ensure that repair requests

be used by the users to communicate

from users are promptly relayed to

with the medical equipment maintenance

technical personnel for timely response.

department so there is no confusion

Many maintenance programmes have

about which specific piece of equipment

also found it helpful for technical

is being reported.

personnel to regularly contact clinical

personnel, preferably in person, to inquire

When doing IPM procedures, a label

about any equipment-related problems

indicating the date the work was done

they are experiencing. In this way the

and the procedure that was performed

technical personnel become accepted as

should be applied to the equipment for

part of the clinical team.

two reasons:

• To communicate with clinicians and

overview Ultimately, effective communication with

engineers and biomedical equipment

the clinical users leads to:

technician can be instrumental in working

• Clinical staff understanding the

with clinicians to resolve these issues.

reason behind inspecting and

They are responsible for providing them

maintaining equipment and the

with adequate training (or retraining if

benefits of such a programme.

appropriate) on the operation of a device

• The clinical engineering department

and working with the users to identify

being kept well informed of a

factors leading to use error.

device's elapsed usage time for the

determination of PM frequency.

A wel -trained user is aware that when

• The clinical users being alert to

preventive maintenance, performance

changes or issues with the equipment

or safety inspections are done, the

and immediately contacting the

equipment is adjusted to test its various

clinical engineering department

modes of operation. Therefore, the settings

when such problems are detected.

that the user may be used to having left

• The clinical staff being able to locate

untouched on their equipment wil have

all essential equipment, and inform

been changed and they should check the

technical personnel of location.

settings and adjustments before using it

• Devices in storage being brought out

with patients once again.

for inspection.

• Minimal time being spent in the

Additionally, if users are expected to

department.

provide basic, routine maintenance on a

• An improved working relationship

device, the clinical engineering department

with the clinical department.

is responsible for training them on the

correct procedures. The overall result

Providing clinical users with a list of the

wil be a user who feels ownership for

scheduled IPM work a few weeks in

the equipment, takes good care of the

advance, a copy of IPM results, or a list

equipment, operates (and maintains) it

of problems identified, solved or remain
wel , leading to a reduced workload for
to be addressed, are just a few examples
the clinical engineering department and
of good communication practice.
improved lifespan for the equipment.

5.3.9 Managing use and user error

5.3.10 Travel

The work of clinicians, including the use
Travel is an important component of
of health technology, can be viewed as
an effective maintenance programme.
a series of activities intended to achieve
If extensive travel between facilities is
a particular clinical objective: diagnosis,
required or the accessibility of facilities is
treatment, monitoring or life support..
difficult, there wil be significant effects on
However, a user may be unable to meet
work assignments, productivity standards,
this objective due to ‘use error’, a problem
vehicle and other travel expenses, etc. For
related to the use of a medical device. This
example, in remote areas, it may take a
is distinct from the term ‘user error’, which
day or more to travel to a local clinic. Thus,
implies that the user of the device caused
travel time should be considered when
the problem. Investigation of use error
planning maintenance activities. However,
includes consideration of the user, the
it may be also reasonable to develop and
patient, the device, the environment and
support user maintenance where it may be
other systemic factors that may block the
difficult to transport the tools, equipment,
achievement of a clinical objective. The
and technician to the site.
root cause of user error is typically easier
to identify. However, in both cases clinical

5.4 Performance monitoring

This indicator is used to measure the
productivity and effectiveness of the IPM
For effective management of the
staff, the ability of the technical personnel,
maintenance programme, it is important to
and the adequacy of the staffing
measure performance. Most performance
levels. IPM completion rates for each
measures do not have a standard or
technician must take into consideration
benchmark to compare with. In such
the expected time it takes to complete an
cases the manager should monitor
IPM procedure, so the technician is not
performance over time, investigate
overloaded, or underloaded, with work.
any significant trends, and identify

opportunities for improvement. It is also

5.4.2 Equipment location rate

important to communicate regularly with

The proportion of equipment scheduled

colleagues who are managing similar

to be inspected in the assignment

programmes. By comparing performance

period but not located before the end

data, managers can identify and take

of the inspection period is known as the

advantage of improvement opportunities.

equipment location rate. This indicator

Those with the financial resources may

primarily measures the accuracy of the

consider subscribing to a benchmarking

inventory database in the CMMS system.

service that will support detailed

It also provides an indication of the

performance monitoring.1

effectiveness of the policies to keep the

inventory accurate, as well as measuring

Several important performance measures

the quality of communications between

are described below, but note that without

clinicians and the medical equipment

a CMMS it is very difficult to calculate

maintenance department, particularly

some of these measures. However it

when equipment is moved, loaned or put

is important to conduct some sort of

into storage.

performance monitoring on a regular

basis in order to to identify opportunities

5.4.3 IPM yield

for improvement.

IPM yield is the percent of scheduled IPM

procedures performed where problems

5.4.1 Completion rate of assigned

were found that affected equipment

IPM

operation or safety (note cosmetic

The completion rate is percentage

problems which do not affect function or

of procedures completed. It can be

safety are not included). This indicator

measured at the end of an assignment

measures the general reliability of the

period (e.g. monthly, bi-monthly or

medical equipment at the facility. When

quarterly). A good completion rate goal is

individual models of equipment are

to be above 90%. This measure could also

analyzed it can be useful to compare

be calculated to evaluate the completion

the reliability of one model against

rate of each priority group, starting with

another. Furthermore, it is a measure

the highest priority group . The highest

of the effectiveness of the maintenance

priority devices should have the highest

programme; if equipment is being well-

completion rate goal, e.g., over 95%, with

maintained the percentage wil be low.

lower priority groups having lower goals.

Alternatively, if problems are discovered

upon inspection that should have been

1 The Association for the Advancement of Medical Instrumentation offers *AAMI's* detected by the user, the percentage

Benchmarking Solution, which is a online self-assessment tool for clinical will be higher than anticipated. As such,

engineering (www.aami.org/abs). It supports performance monitoring, assessment of best practices, and performance improvement.

IPM yield may also indicate how well

ECRI Institute (www.ecri.org) of ers *Biomedical Benchmark,* which provides clinicians report problems they find with

several valuable tools for medical technology management, including detailed benchmarking capabilities for medical equipment maintenance activities.

equipment.

 5.4.4 IPM productivity

• *Repair time.* The time between the The productivity and effectiveness of the

start and finish of repair.

IPM staff is an important management

• *Downtime.* The percentage of time

measure. By modifying department

that a device is out of service.

policies, levels of training, test equipment,

• *Delinquent work orders.* Work orders

and/or forms or procedures, great

not completed within 30 days.

improvements in individual or group

productivity can be achieved. However,

this can be managed only if targeted

5.5 Performance improvement

activities are measured. The most

important IPM productivity measurement

For a maintenance programme,

in use today is IPM productivity.

performance improvement applies to

every aspect of the programme, with the

IPM productivity is an expression of

ultimate objective of improving patient

the actual time it takes an individual

care. The performance improvement

to complete a single scheduled IPM

process has the following steps:

procedure divided by the time the IPM

procedure is expected to take. The actual

1. *Identify opportunities for* time taken does not include preparation

improvement. This is one of the

or set-up time, merely the actual time

outcomes of careful and thorough

it takes the technician to perform the

performance monitoring as described

individual procedure on each device.

above.

The results from individual inspections

2. *Identify best practices.* These are can then be added up to measure the
actions that have been recognized
daily, weekly or monthly productivity
within the profession as leading
levels. The number for all technicians
to improved performance. They
can be added to calculate the results
are found in clinical engineering
for an entire maintenance programme.
literature and through collaboration
The expected IPM completion time is
with professional colleagues.
initially obtained from outside sources
3. *Improve performance.* Performance
such as the manufacturer's maintenance
improvement projects should
manual. Eventually, after several years of
be based on best practices. The
experience and collecting accurate data,
aspect of performance selected
you can use past experience to guide
for improvement should be closely
expected completion times.
monitored until the desired level of
performance is achieved.

5.4.5 CM performance measures

In addition to the measures already
Specific changes should be measured
mentioned, there are certain measures
systematical y to determine if the changes
that may be recorded to specifically
improve performance and quality. This
monitor CM performance. For example:
can be done by: a) carefully measuring
• *Mean time between failures.* The
the performance and quality indicators
average time elapsed between
for several measurement periods (months
failures.
or quarters); b) making a change in the
• *Repeated failures.* The number of
way things are done; and c) continuing
failures within a specified period of
to measure the performance and quality.
time.
If the new procedures demonstrate
• *Response time.* The time between
positive improvements then the change
a request for service and the start
was an effective one. If indicators do not
of repair.
improve, revisit the original performance

analysis, adjust accordingly and repeat
the technicians operate (e.g. install a
the process. This systematic approach
remote workshop, purchase automated
of managing programme performance

test equipment, upgrade to a CMMS
improvement can have a very positive
system etc.), the cost of these changes
impact over a period of several years.
can be justified, the changes will be
wel accepted by the staff, and further
Additionally by measuring the improve-
systemic changes can continue to be
ment in performance and quality after
made.
making changes to the system in which

6.1 Inspection and preventive
of the IPM process. If the IPM activities
maintenance
or related repairs are not accomplished
in a certain pre-defined period, the work
6.1.1 IPM procedures
order should be left open and the staff
Using the correct and appropriate
should continue to locate the device and
procedures for equipment maintenance
inspect or repair it as soon as reasonably
can make the difference between
possible. Higher priority devices not
having reliable and properly functioning
inspected in previous IPM periods should
equipment and not. As discussed in
be located and inspected first. Appendix
section 5.3.1, the procedures used in
A.5 presents a sample policy regarding
performing IPM activities should be
corrective actions identified during
defined prior to execution of the inspection
preventive maintenance.
or maintenance work, through a careful
review of each type of equipment (or
model).

6.2 Corrective maintenance

Most IPM procedures are completed
6.2.1 Troubleshooting and repair
by technical personnel from the clinical
Identification of a device failure occurs
engineering department. In some cases,
when a device user has reported a
however, routine and easy to perform
problem with the device. As mentioned
tasks are completed by the user. This
earlier, it may also occur when a
saves time for technical personnel to
technician in the clinical engineering
perform more technical y complex and
department finds that a device is not
critical tasks and also provides the user
performing as expected during IPM.
with a sense of ownership. The type
of inspection the user might perform
In order to return equipment to

would be pre-use or daily checks, where
service as quickly as possible, efficient
required. Examples of this might be daily
troubleshooting is required to verify the
calibration of portable blood glucose
failure and determine its origin. In some
monitors, daily testing of defibrillators
cases the technician will find that the
or checking the standard calibration
device itself has failed and must be
of laboratory equipment. It is the
repaired. The technician then determines
responsibility of the clinical engineering
what steps are necessary to correct the
department to train the user to perform
problem and return the device to full
these tasks. See section 5.3.9 for further
functionality. The technician initiates
information on user interaction.
the corrective maintenance, performing
some steps themselves and making use
Appendix A.3 provides a sample policy on
of in-house expertise or external service
inspection and preventive maintenance
providers when necessary. This corrective
procedure.
maintenance may be accomplished at
various levels:

6.1.2 Problem identification

When IPM identifies a problem, the device

• Component level. Component-level
can either be set aside for later repair, so
troubleshooting and repair isolates
the IPM work can continue on schedule,
the failure to a single, replaceable
or the repair can be completed as part
component. In electrical devices,

mechanical devices, and for discreet
In some cases, the technician wil find
components of electronic devices
that the device performs within its
(such as resistors or capacitors in
design specifications, as defined by
an electronic circuit, or fuses) this
the manufacturer. In such instances,
is often the most effective repair
it is necessary to communicate with
approach. In relation to electronic
the device user and examine the work
devices, however, component-level
environment to determine why the device
repair may be time-consuming
did not function as expected. See section
and difficult. Modern electronic
5.3.8 on managing use error and section
circuit boards (digital circuit
6.2.2 on factors affecting equipment
boards, especially) are frequently

failure for further information.

not repairable at the component

level. In those cases board-level or

6.2.2 Factors affecting equipment

even system-level repair need to be

failures

considered.

When investigating an unexplained failure,

• *Board level.* For electronic devices, environmental factors should be taken into

it is common to isolate failures to a

due consideration. For example, medical

particular circuit board and to replace

devices that require electrical power may

the entire circuit board rather than a

be adversely affected by power issues.

given electronic component.

Ideal y, electrical power should have a

• *Device or system level.* In some cases steady voltage (of the appropriate value);

even board-level troubleshooting

be free of transient distortions, such as

and repair is too difficult or time-

voltage spikes, surges or dropouts; and

consuming. In such cases it can be

be reliable, with only rare loss of power.

more cost-effective to replace the

Unfortunately, these ideal characteristics

entire device or subsystem.

do not always exist in many developing

countries. Technical personnel should

It is important to choose an appropriate

col aborate with those responsible for the

level of maintenance for each situation.

electrical power system in the health-care

This is dependent on the availability of

organization to help make the system

financial, physical and human resources

function as effectively as possible.

as well as on the urgency of a particular

This may include purchasing voltage

repair request. For high-priority cases,

regulators, installing uninterruptable

for example, device-level repairs may be

power supplies (UPS), using surge

preferred. When more time is available,

protectors, and avoiding connecting

board- or component-level repair may

extension leads/plug boards in series.

be feasible. If component-level repair

Furthermore, technical personnel should

is proposed, part replacement may be

work with the facility personnel to ensure

necessary. For this approach, there are

that a functional back-up generator is

a few options from which to choose.

in place and that the switch to auxiliary

The replacement can be made with

power is made in under 10 seconds.

specialized parts from the manufacturer,

Another alternative may be to select

with generic parts of the same or higher
and purchase equipment that is battery
specifications (e.g. fuses), or with spares
operated. When considering acquiring
reclaimed from non-functional or obsolete
new equipment, it is also important for
equipment (only after thorough risk-
the technical personnel to ensure that
assessment and permission of the clinical
the electrical power system is capable
engineering manager).
of supporting it. When it cannot, it often
makes sense to opt for less sophisticated
and more robust equipment.

 Similarly, technical personnel should be

6.3 Reporting

aware of how medical devices interact
with other utility systems (e.g. medical
For IPM activities, the technician typical y
gas and vacuum systems, temperature
has a detailed checklist to follow in
control and ventilation systems, water
order to record the results. Having such
supply, information technology and
a checklist also serves as a reminder
communication infrastructure, etc.).
of each step in the IPM process and
And, once again, they should collaborate
thus helps avoid skipping or overlooking
with others in the organization to optimize
specific steps. Recording measurements
the ability of the utility systems to support
and documenting the final results (either
medical equipment.1
as ‘pass/fail’ or numeric values) aids in the
execution of future maintenance work,
Unique aspects of the physical
including repairs. Having the last few sets
environment, such as high temperature
of IPM checklists on-hand for reference
and humidity, can adversely affect
during maintenance is extremely helpful
medical equipment designed for use
for decision-making. For example, for
in temperate climates or controlled
equipment with therapeutic energy
environments. Maintenance procedures
output, including the energy readings
in a particular country or region may
from the last few inspections on the next
need to be adjusted based on these local
inspection form helps identify potential
factors.
problems, as equipment energy levels
may slowly drift over time. Additionally,
The age and condition of the health-care
knowing when routine maintenance
facility may also play a role in medical

parts were last replaced helps identify
equipment failure. Over time, utilities
if or when the parts should be replaced
systems will degrade and may become
again, and helps explain the condition of
overloaded and/or outdated. Older
the parts during the current inspection.
facilities will have been built to older
Several example forms which can be
standards. Even new facilities may not
used for IPM are provided in Appendix D.
meet al applicable standards. Therefore,
it is often necessary to test the utility For CM, the technician records what
infrastructure rather than to assume it is
actions were taken, including the time
functioning appropriately.
and the cost of those actions.

6.2.3 Inspection and return to service

After completion of repair, it is essential

6.4 Safety

to conduct a performance and safety
inspection, and in some cases a re-
There are various safety aspects to
calibration may be required. These
consider when implementing a successful
activities wil measure the performance of
and effective maintenance programme,
the device and allow for any adjustments
such as the safety of technical personnel
necessary to return the equipment to full
while performing maintenance, safety
functionality. Once this is complete, the
of the user following maintenance, and
device may be returned to use in patient
general infection control.
care.
The safety of equipment maintenance
personnel is fundamental. Therefore, it
1 It is important for clinical engineers and biomedical equipment technicians to have is important to have a 'lock out / tag
a working knowledge of utility systems and facility infrastructure. An article that out' policy to protect personnel from
provides an overview of these topics can be found in Issue 4 of Revista Ingeniería Biomédica (Colombia) (http://revistabme.eia.edu.co/numeros/4/index.html).
unexpected activation of equipment

and release of stored energy. This policy
(In the absence of electrical safety test
ensures that when working on electrical
equipment, technical personnel must
equipment it is essential to disconnect
rely on careful repair techniques and
it from the electrical power source. One
simple electrical tests to verify device
or more physical locks may be applied
integrity). Clinicians should be advised
to keep the power source disconnected
to check the settings of the device and to

('lock out') so that it is not inadvertently
perform basic operational checks prior
reconnected before the repair is
to using the device with patients. When
completed. When it is not possible to
direct communication is not possible, a
physically lock out the power source,
prominent note should be placed on the
prominent signage should be posted ('tag
device so that it is not used without being
out').
checked by the clinician.
Furthermore, personnel should be aware,
Lastly, when working in the clinical
prior to performing maintenance work, of
environment, technical personnel should
particular medical technologies that may
be aware of infection control risks that
present special hazards such as chemical
they might encounter (patients with
hazards from chemotherapeutic agents
airborne infections such a tuberculosis,
and from other sources, radiation hazards
for example) and, if there is any doubt,
from radiation-generating equipment
they should ask clinicians in the area. In
and radiopharmaceuticals, magnetic
particular, if asked to work on a medical
field hazards from magnetic resonance
device that appears to be contaminated,
imaging (MRI) equipment, hazards from
they should request assistance in cleaning
compressed gas cylinders, etc. Training
the device from the clinical user, who will
in personal protective equipment (PPE)
have knowledge regarding the potential
and techniques that will allow technical
contaminants and their associated
personnel to work safely in hazardous
hazards. Additional y, technical personnel
conditions are critical. It is preferable
should be aware of infection hazards
to have PPE readily available within
that their work might create for patients.
the clinical engineering department for
For example, patients with compromised
hazardous maintenance.
immune systems (certain organ transplant
patients, patients with AIDS, and others)
Fol owing maintenance, especial y after
or otherwise susceptible to infection (such
procedures that may have affected the
as premature infants) can be severely
safety features of a medical device,
affected by moulds and spores disturbed
technical personnel should verify that
and dispersed by maintenance activities
the device is safe to use, mechanically
in the clinical environment. Again, when

and electrically. Particular attention is

in doubt, equipment maintainers should

given to electrical safety for medical

communicate with clinicians about

devices such that ground resistance and

potential risks and ways to manage those

leakage currents are measured to ensure

risks. See Appendix A.6 for a sample

that they are within applicable limits.

infection control policy.

Timely and economical maintenance

can be designed and executed. However,

activities maximize the value of health

the programme must be considered an

technology resources, which is especial y

integral part of health-care delivery with a

important when resources are limited.

minimum set of resources designated to

When the various financial, physical and

fulfil the tasks outlined by the programme.

human resource aspects are carefully

Only in this way will patients have access

examined, even with certain resource

to the medical equipment that can provide

constraints, a successful programme that

them with an accurate diagnosis, effective

suits the needs of a particular context

treatment or appropriate rehabilitation.

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• *AAMI benchmarking solution* (www.aami.org/abs)

• *Electrical safety manual* (www.aami.org/publications/books/esm.html)

• *Computerized maintenance management systems* (www.aami.org/publications/

books/cmms.html)

• *Medical equipment management manual* (www.aami.org/publications/books/mem.

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• *Medical electrical equipment standard 60601-1* (www.aami.org/publications/

standards/60601.html)

ECRI Institute (www.ecri.org):

• *Health devices system* (www.ecri.org/Products/Pages/Health_Devices_System.aspx)

• *Biomedical benchmark* (www.ecri.org/Products/Pages/BiomedicalBenchmark.aspx) Joint Commission/Joint Commission International:

• *Accreditation standards, United States* (www.jointcommission.org)

• *Accreditation standards, international* (www.jointcommissioninternational.org) National Fire Protection Association (www.nfpa.org):

• *Standard for health care facilities* (NFPA 99)

• *National electrical code* (NFPA 70)

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• 24×7 (www.24x7mag.com)

• American College of Clinical Engineering (www.accenet.org)

• American Hospital Association (www.aha.org)

• Biomedical Instrumentation and Technology (www.aami.org/publications/BIT/)

• El Hospital (www.elhospital.com)

• Engineering World Health (www.ewh.org)

• International Electrotechnical Commission (www.iec.ch)

• Journal of Clinical Engineering (journals.lww.com/jcejournal) Online discussion groups:

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Medical equipment maintenance programme overview Appendix A

Sample policies and procedures

The following samples are provided to support the development of medical equipment maintenance policies and procedures in a hospital, health centre or other health facilities. The samples should be adapted and modified according to the specific needs and circumstances of any given institution, the relevant resource context and local environment.

A.1 Risk-based biomedical equipment management programme A.2 Initial testing and evaluation

A.3 Inspection and preventive maintenance procedure A.4 Work order system for corrective maintenance A.5 Corrective actions identified during preventive maintenance A.6 Infection control

Appendix A 1

Risk-based biomedical equipment management programme Equipment inclusion criteria have been developed to evaluate each piece of equipment in use at a hospital or health facility. The following details a modified version of the Fennigkoh and Smith model (see reference 6) where a numerical value has been assigned to each device type by classifying its equipment function, clinical application and required maintenance. Adding the number from each subgroup and adding or subtracting a factor based on equipment failure history yields an equipment management (EM) number.

EM number equation:

EM # = Function # + Application # + Maintenance # + History #

Equipment function

Includes various areas in which therapeutic, diagnostic, analytical and miscellaneous equipment is used.

Category

Function description

Point score

Therapeutic

Life support

10

Surgical and intensive care

9

Physical therapy and treatment

8

Diagnostic

Surgical and intensive care monitoring

7

Additional physiological monitoring and diagnostic
6

Analytical

Analytical laboratory

5

Laboratory accessories

4

Computers and related

3

Miscellaneous

Patient related and other

2

Physical risk associated with clinical application Lists the potential patient or equipment risk during use.

Maintenance requirement

Point score

Extensive: routine calibration and part replacement required 5

Above-average

4

Average: performance verification and safety testing 3

Below-average

2

Minimal: visual inspection

1

48

Medical equipment maintenance programme overview **Equipment incident history**

Any information available regarding service history that can be considered when evaluating the device type to determine an EM number.

Average equipment failures

Factor

Significant: more than one every 6 months

+2

Moderate: one every 6–9 months

+1

Average: one every 9–18 months

0

Minimal: one every 18–30 months

-1

Insignificant: less than one in the past 30 months

-2

Included devices

All devices with a total EM number 12 or more will be included in the programme and scheduled for inspections and preventive maintenance. During the acceptance testing, any new device will be included in the programme if the device has been previously evaluated and classified for inclusion. If the device has not been previously evaluated, a new device classification will be created. It will be evaluated according to the outlined procedure to produce an EM number and will be included in the programme if appropriate. If included, a performance assurance inspection and preventive maintenance procedure will be written for the new device.

Maintenance interval

The maintenance requirement values are also used to determine the interval between each inspection and maintenance procedure for each device type.

• Al devices classified as extensive (characteristic value of 4 or 5) are given a preventive maintenance interval of six months.

• Devices with average or minimal requirements (values of 3, 2 or 1) are scheduled for preventive maintenance annually.

• Devices with an EM number of 15 or above wil be scheduled for inspection at least every six months.

• Devices with an EM number of 19 or 20 will be given an inspection interval of four months.

Devices not included in the programme

Al patient care-related equipment including therapeutic, monitoring, diagnostic or analytical equipment not included in the programme, because it did not receive an EM

number of 12 or above, may still be included in the hospital’s biomedical equipment inventory and be covered on a repair-only basis.

Equipment classification examples

Equipment Clinical

Maintenance Incident

Inspection

Device description

function

application requirement history

EM #

Class

frequency

Anaesthesia machine

10

5

5

0

20

I

T

Anaesthesia vaporizer (enflurane/

9

5

3

-2

15

I

S

ethrane)

Arthroscopic surgical unit

9

4

2

-2

13

I

A

Breast pump

3

4

3

-2

8

N

-

Aspirator, mobile

8

5

4

-1

16

I

S

Blood warmer

9

4

3

-1

15

I

S

Bone saw

9

4

2

-2

3

I

A

Blood pressure module

7

3

2

0

12

I

A

Camera, video, medical

6

3

3

0

12

I

A

Cast cutter

2

4

3

-2

7

N

-

Cast cutter vacuum

2

2

3

-2

5

N

-

Cardiac output computer

7

3

2

0

12

I

A

Computer, micro (pc)

3

3

1

-2

5

N

-

Cryosurgical unit

9

4

3

-1

15

I

S

Defibrillator/monitor

9

5

4

0

18

I

S

Electrocardiograph, 3-channel

6

3

5

2

16

I

S

Endoscopic video system

6

3

3

0

12

I

A

Electrosurgical unit

9

4

3

0

16

I

S

Fetal monitor

7

3

3

0

13

I

A

Humidifier, heated

8

3

3

1

15

I

S

Hypo-hyperthermia machine

9

4

5

0

18

I

S

Light, surgical portable

2

4

3

-1

8

N

-

Light source, fibre optic

7

3

3

-2

11

N

-

Microscope, opthalmic slit lamp

6

3

3

-2

10

N

-

Class Inspection frequency

I = Included

A = Annual

T = Three-yearly

N = Not included

S = Semi-annual

Initial testing and evaluation

Purpose

To assure that all clinical equipment is inspected prior to its initial use.

Policy

Al clinical equipment coming into the hospital is tested before initial use and appropriately added to an inventory. These tests, evaluations and inventories are documented. All clinical equipment fal ing under the responsibility of the clinical engineering department is covered by this policy, regardless of ownership, and must pass the incoming inspection before it will be allowed into the hospital. Examples of ownership categories are:

• Rental/leased equipment

• Physician-owned equipment

• Donated/loaned equipment

• Hospital-owned equipment

Procedures

A. Hospital-owned equipment:

1. When notified that new clinical equipment is received in the hospital, the clinical engineering department will initiate a work order.

2. The clinical engineering department will ensure that the new equipment is inspected for:

a. Presence of all accessories required for proper operation.

b. Presence of operators' manuals and technical service manuals, and schematics, if applicable.

c. Proper operation of the equipment. Performance specifications in the manufacturer's service literature should be used if available.

d. Clinical alarm functionality and audibility, if applicable.

e. Passage of electrical safety requirements, if applicable.

f. Inclusion into, or exclusion from, the equipment

management programme.

g. Compliance on label ing of equipment, to ensure that the equipment has been “evaluated for safety and suitability for intended use” by a nationally or internationally recognized testing laboratory.

3. If equipment passes all required inspections, the technician will affix a clinical equipment maintenance inspection sticker, or other means of identification, in a visible location on the device.

4. The clinical engineering technician who performs the inspection is responsible for ensuring the completion of the initial inspection documentation. If the technician determines that an in-service orientation/training would be beneficial, the technician wil make a recommendation to the hospital education department or the department manager. Should a manufacturer in-service demonstration be required, the technician will assist in coordinating this effort with the hospital education department.

B. Testing of devices brought in for demonstration or trial evaluation The hospital is responsible for the safety of all patients, staff, and visitors: equipment for loan, evaluation or demonstration is tested prior to its use in the hospital, unless an emergency dictates otherwise. In this instance, the user should ensure with reasonable certainty that the equipment is in safe working condition before operating. If the equipment is to remain in the hospital subsequent to its emergency use, it must be safety tested by the clinical engineering department.

1. Al electrical equipment that passes the clinical engineering safety inspection will have a clinical equipment maintenance sticker affixed in a visible location, or equivalent, indicating that it has been inspected, and is safe for use in the hospital. (Certain battery-operated devices may be excluded from the preventive maintenance programme, and will not have a sticker affixed. Devices included in the programme, but that do not require regular preventive maintenance, will also receive a “PM Exempt” sticker).

2. Any equipment that fails the clinical engineering safety inspection wil be returned to its originating source with a description of the failure. Such equipment/device will be prohibited from being used in the facility until it has been repaired and satisfactorily passes the safety inspection.

C. Equipment intended for use in a clinical laboratory application Vendor provided equipment in exchange for the purchase of reagents or consumables must be approved by hospital management, the clinical laboratory, or pathology department manager and safety tested prior to being placed into service. Hospital technical staff is not responsible for the maintenance of this equipment.

Medical equipment maintenance programme overview Appendix A 3

Inspection and preventive maintenance procedure

Equipment to be covered by the programme wil typical y include: life support equipment, laboratory equipment, surgical and critical care equipment, imaging equipment, equipment which could cause patient injury or death if it fails, equipment required to be maintained by regulations, equipment on an outside vendor maintenance programme, equipment under lease where maintenance is part of the lease, and equipment under warranty.

Procedure

1. All equipment due for maintenance needs to be identified one month prior to the maintenance date. The list of maintenance tasks can be generated automatically by a Computerized Maintenance Management System (CMMS), if in place.

2. Parts required for preventive maintenance are ordered and made available for the equipment in this period.

3. The inspection and preventive maintenance (IPM) tasks wil be assigned to specific biomedical technicians.

4. Work orders will be generated and distributed to the assigned technicians.

5. Maintenance wil be performed in accordance with the established IPM procedure.

These IPM procedures wil be based on manufacturer’s recommendations, industry recommendations and facility experience.

6. The assigned technician will document on the work order the inspections and maintenance performed and any other important observations.

7. When the IPM is completed successful y, the equipment wil receive an IPM sticker or other identification denoting its maintenance status.

8. When the IPM and documentation is completed, the work order will be updated in the records and/or the CMMS.

9. If scheduled work cannot be completed (i.e. parts are needed, equipment is in use, equipment cannot be located), the reason is documented on a work order.

This work will be followed up at a later date.

10. When scheduled maintenance is performed by an outside vendor, the biomedical engineering department wil notify the vendor and schedule the maintenance service. When maintenance and documentation is completed, the work order is subsequently updated in the records and/or the CMMS.

11. Life support equipment due for maintenance but still in use by patients will be WHO Medical device technical series

scheduled after it is removed from the patient. The technician wil work closely with the clinical department to schedule the maintenance as soon as possible.

12. Equipment scheduled for IPM but which cannot be located, can be identified as

“could not locate” only after a concerted effort to locate the device has been made, the equipment owners have made every attempt to locate it and the biomedical engineering supervisor/manager has approved the device to be marked in this way.

13. If the equipment has not been located for two consecutive maintenance cycles, it will be removed from service and deleted from the records, and/or deactivated in the CMMS.

14. To assure IPM quality technician competency and the correct execution of IPM, procedures and practices need to be evaluated by clinical engineering management.

15. Maintenance completion rates, lists of equipment unable to be located, PM yield rates and other quality or performance related statistics will be reported to the relevant Safety Committee and the clinical engineering department staff at least quarterly.

Longer or shorter preventive maintenance intervals are adopted after documented justification based on previous PM yield data, relevant safety information and other service history records.

Medical equipment maintenance programme overview Appendix A 4

Work order system for corrective maintenance

The clinical engineering department has adopted a standard work order system for all departments requesting maintenance on clinical equipment. When a malfunction occurs with a piece of clinical equipment that is encompassed within the programme of the clinical engineering department, the using department shall notify clinical engineering during rounds, by telephone, by on-line/web request, by interdepartmental mail or by bringing the device to the clinical engineering office.

Purpose

To provide guidelines for the receipt and processing of clinical engineering service requests.

Procedure

1. Upon receipt of the request, typically a work order will be initiated. This includes priority designation and delegation of the work order to a technician for completion.

Both will normally be determined by the appropriate clinical engineering manager.

Input from users is encouraged with regard to priority assignment. The priority categories are as follows:

I. Emergency urgent

• This describes situations of dire need and severe safety concerns for patients, visitors or staff. The lack of immediate action could cause severe consequences for the hospital and/or potential loss of life or disability.

• Emergency requests are accepted by phone or verbal y and wil be addressed by the chief biomedical engineer.

• Under uch circumstances, documentation will be completed at the earliest possible opportunity.

• Should an outside vendor be required to rectify the problem, the chief biomedical engineer will test and evaluate the equipment upon return, prior to being taken into service.

II. Urgent

• This category is used for failures that require immediate attention because the operation of the hospital/facility is compromised.

• A work order can be hand-carried to the clinical engineering department.

The response to the request will be as soon as possible, only an emergency request will pre-empt this work order.

III. Routine

• This describes an action that needs to be taken, but the situation does not compromise the primary function of the hospital/facility.

• Routine work orders can be sent through the hospital/facility interdepartmental mail system.

• The requesting department will be notified once the order has been received and the work has been scheduled.

IV. Deffered

• Routine requests may be deferred based on workload or priority. No work order may be deferred for more than 10 normal working days without the approval of the clinical engineering manager.

2. Information to identify the equipment, the respective department and to describe the problem should be provided on the work request, by the person originating the request for service, or by the technician. This may include the following: a. Inventory identification number

b. Cost center (usually the user department)

c. Equipment description

d. Telephone number

e. Name of contact

f. Location of equipment

g. Description of the problem

Upon completion of the work, the technician will complete the work order within one day, including all information relating to the service request. All work orders are dated and logged for record keeping. In the event that a work order cannot be completed in the requested time, or within twelve business days, the technician wil notify the request originator or department manager and inform them of the reasons that the equipment repair will be delayed, and provide them with an estimated time of repair. It is the responsibility of each clinical engineering technician to follow-up on such situations as needed and personally contact the request originator or department manager if necessary.

Medical equipment maintenance programme overview Appendix A 5

Corrective actions identified during preventive maintenance The clinical engineering department performs preventive maintenance procedures on a timely basis as part of the hospital's equipment management plan. Corrective actions arising during preventive maintenance procedures will be documented appropriately.

Purpose

To ensure corrective actions are performed and documented appropriately when found during preventive maintenance procedures.

Procedure

A. No problem found during preventive maintenance of a medical device 1. Once the preventive maintenance procedure is performed, the technician will complete the preventive maintenance work order form.

2. The technician wil affix an updated maintenance sticker, or other record of inspection, on the device.

Note: if the PM work request is completed in a month later than the scheduled month, the technician will date the sticker to correspond with the month the work request was completed.

3. The technician will return the device to service.

B. Problem found during preventive maintenance of a medical device 1. If a problem is determined to be minor, the preventive maintenance procedure can be completed and the device cannot be returned to service, the technician should follow the following steps: (Example: a power cord has a cut in the covering).

a. The technician should perform the preventive maintenance procedure.

b. The technician should complete the PM work order form.

c. The technician should affix an updated sticker on the device.

Note: if the PM work request is completed in a month after the scheduled month, the technician will date the sticker to correspond with the month the work request was completed. The due date should reflect the next due date based upon the last due month and the appropriate interval for the device.

d. The technician should initiate a corrective work order request, affix a label to the device indicating it is out of service and inform the user department of the delay in return to service of the device.

2. If a problem is determined to be minor, the preventive maintenance procedure can be completed and the device can be returned to service, the technician should fol ow these steps: (Example: a hose bracket for an anaesthesia machine is broken or a cosmetic label has fallen off).

a. The technician should perform the preventive maintenance procedure.

b. The technician should complete the PM work order form.

c. The technician should affix an updated maintenance sticker on the device. Note: if the PM work request is completed in a month after the scheduled month, the technician will date the sticker to correspond with the month the work request was completed. The due date should reflect the next due date based upon the last due month and the appropriate interval for the device.

d. The technician should return the unit to service.

e. The technician should initiate a corrective work order for eventual follow-up action when the device is available and take appropriate actions to complete the request

3. If a problem is determined to be more than minor and the preventive maintenance procedure cannot be completed, the technician should complete the following steps: (Example: the flow control module on a mechanical ventilator is damaged).

a. The technician should initiate a corrective work order referencing the preventive work request number, affix a label to the device indicating it is out of service and inform the user department of the delay in return to service of the device.

b. The technician should complete the preventive maintenance work order and must reference the corrective work order number.

c. Upon completion of the corrective action, the technician must resume the preventive maintenance procedure, document that a preventive maintenance procedure was completed and then complete the corrective work request.

d. The technician should affix an updated maintenance sticker on the device.

Note: the completion date wil be the date the PM work request documentation is completed in the work order system. For example, a PM work request was completed in October and the CM work request was opened and carried over into November. The PM sticker should reflect the October date coinciding with the PM work order. The due date should reflect the next due date based upon the last due month and the appropriate interval for the device. The technician wil complete the CM work order and document the date the CM work was done.

e. The technician should return the device to service.

Medical equipment maintenance programme overview Appendix A 6

Infection control

All clinical engineering employees will be aware of current hospital policies regarding infection control. Employees wil not knowingly expose themselves or others to any types of infectious waste.

Purpose

To provide all employees with a safe, clean working environment, to protect clinical engineering technicians from contaminated equipment.

Procedure

General Precautions

1. Visibly contaminated equipment will not be accepted for repair until adequately cleaned by the appropriate department. Appropriate personal protective equipment is worn to handle equipment.

2. Al clinical engineering technicians wil observe isolation guidelines as wel as the dress and scrub procedures for the area in which they are working. Clinical engineering technicians should not enter 'isolation rooms' or 'restricted areas'

without obtaining permission from the charge nurse.

3. All clinical engineering employees will attend annual infection control education.

This training will be documented in the employees' personal training record in the clinical engineering department.

4. Hand-washing is required whenever:

a. Hands become contaminated with blood or body fluids.

b. Protective gloves are removed.

c. Between patient contacts.

d. Eating, drinking, applying cosmetics and handling contact lenses are prohibited in areas where there is a risk of occupational exposure to blood or body fluids.

Personal protective equipment (PPE)

1. Disposable gloves are available, within the clinical engineering department, for all workers at risk of exposure for use at their discretion or as required.

2. Eye protection and/or a facemask will be worn whenever handling equipment that puts the employee at risk of occupational exposure to blood or body fluids through splashing.

3. Personal protective equipment, (i.e. gowns, gloves, masks and goggles) will be supplied by the user department whenever needed.

4. Contaminated supplies, (i.e. gowns, gloves, masks and absorbent towels) are to be placed in sturdy, plastic bags and tightly closed for appropriate disposal.

Equipment precautions

1. All equipment containing serviced filters will have the filters cleaned or replaced according to manufacturer recommendations.

2. Gloves wil be worn during non-HEPA (high-efficiency particulate air) filter changes.

These filters will be placed in normal waste.

3. Any equipment containing a HEPA filter requires that gloves, particulate respirator, gown, and protective eyewear are worn. These filters will be disposed of as for infectious waste.

4. All replaced filters from the clinical laboratory should be considered contaminated and disposed of as infectious waste. Appropriate PPE will be worn.

5. All equipment that needs to be opened and vacuumed or blown clean will be done away from patient care or employee work areas whenever possible. Equipment that can be carried or rolled easily will be removed to the clinical engineering workshop for cleaning. Clinical engineering personnel will wear masks to eliminate the risk of breathing the dust from any machine.

All equipment that cannot be moved from the employee work area will be vacuumed (as opposed to blown clean), so as not to contaminate the work environment.

Examples of inspection and preventive maintenance procedures **B.1 Template**

B.2 Anaesthesia/Analgesia unit (gas machine)

B.3 Centrifuge, table top

B.4 Monitor, ECG

B.5 Pump, infusion

B.6 X-Ray system, mobile

Appendix B 1

Inspection and preventive maintenance procedure

Example form

Equipment type

Name and/or type of equipment

Risk score

Available from the national

Safety inspections/year

Refer to manufacturer's

regulatory agency, or consult

service manual

the FDA.

Programme risk (EM number) Refer to Appendix A.1 to Performance inspections/year Refer to manufacturer's determine risk EM number

service manual

Risk group (equipment

Refer to Appendix A.1 to

PM checks/year

Refer to manufacturer's

function category)

determine category

service manual

Procedures:

List the steps to be taken to perform inspection and preventive maintenance.

Anaesthesia/analgesia unit (gas machine)

FDA risk: 2

Safety insp./Yr.: 2

Programme risk score:

Perf. insp./Yr.: 12

Risk group: Life Support

PM checks/Yr.: 12

Procedures:

1. Inspect exterior of equipment for damage or missing hardware.

2. Inspect the power cord, strain relief and plug/s for any signs of damage.

3. Turn unit off, open user-accessible covers and inspect unit for damage.

4. Clean unit interior components and exterior with vacuum or compressed air.

5. Inspect interior for signs of corrosion or missing hardware. Repair as required.

6. Inspect electrical components for signs of excessive heat or deterioration.

7. Inspect all external quick disconnect O-rings.

8. Inspect condition of all tubing, replace if necessary.

9. Inspect all cables for excessive wear.

10. Inspect inspiratory and expiratory flow valves.

11. Inspect internal circuits by leak testing.

12. Verify correct operation of gas scavenger systems.

13. Verify correct vaporizer calibration.

14. Verify correct flow meter calibration.

15. Verify correct operation of ventilator (rate, volume, flow).

16. Verify correct operation of all buttons, controls, displays and/or indicators.

17. Verify correct operation of unit in all functional modalities.

18. Clean exterior of unit including all accessories, cables, controls and displays.

Appendix B 3

Centrifuge, table top

FDA risk: 1

Safety insp./Yr.: 1

Programme risk score:

Perf. insp./Yr.: 4

Risk group: Diagnostic

PM checks/Yr.: 4

Procedures:

1. Inspect exterior of equipment for damage or missing hardware.

2. Inspect the power cord, strain relief and plug/s for any signs of damage.

3. Turn unit off, open user-accessible covers and inspect unit for damage.

4. Clean unit interior components and exterior with vacuum or compressed air.

5. Clean motor with compressed air. Check brushes if applicable.

6. Inspect interior for signs of corrosion or missing hardware. Repair as required.

7. Inspect electrical components for signs of excessive heat or deterioration.

8. Verify correct operation of lid and safety mechanism. Inspect lid gasket.

9. Verify smooth operation of the timer and correct operation of braking.

10. Verify correct operation of tachometer if applicable.

11. Verify head balance. Check for vibrations and excess noise.

12. Verify correct operation of refrigeration and thermostat if applicable.

13. Verify speed setting using a test photo-tachometer.

14. Inspect motor brushes and armature for wear. Clean out carbon build-up.

15. Lubricate motor and mechanical parts where applicable.

16. Verify correct operation of all buttons, controls, displays and indicators.

17. Verify correct operation of unit in all functional modalities.

18. Clean exterior of unit including all accessories, cables, controls and displays.

Monitor, ECG

FDA risk: 2

Safety insp./Yr.: 2

Programme risk score:

Perf. insp./Yr.: 2

Risk group : Diagnostic

PM checks/Yr.: 2

Procedures:

1. Inspect exterior of equipment for damage or missing hardware.

2. Inspect the power cord, strain relief and plug/s for any signs of damage.

3. Turn unit off, open user-accessible covers and inspect unit for damage.

4. Clean unit interior components and exterior with vacuum or compressed air.

5. Inspect interior for signs of corrosion or missing hardware. Repair as required.

6. Inspect electrical components for signs of excessive heat or deterioration.

7. Inspect patient cable and connectors for mechanical or electrical damage.

8. Verify correct detenting and lead shorting of lead selector switch.

9. Verify vertical gain and calibration pulse. Inspect monitor/diagnostic switch.

10. Verify correct sweep size, linearity, centring, speed and vertical spacing.

11. Verify correct amplifier frequency response and common mode rejection.

12. Verify correct brightness and focus of trace.

13. Verify correct operation of freeze and cascade controls if applicable.

14. Verify accuracy of heart rate meter at 3 points for ±3% accuracy.

15. Verify operation of high and low alarms for correct trigger and response time.

16. Cycle alarms and verify correct operation of audio and visual indicators.

17. Verify correct operation of all buttons, controls, displays and/or indicators.

18. Verify correct operation of unit in all functional modalities.

19. Clean exterior of unit including all accessories, cables, controls and displays.

Appendix B 5

Pump, infusion

FDA risk: 2

Safety insp./Yr.: 2

Programme risk score:

Perf. insp./Yr.: 2

Risk group: Patient Support

PM checks/YR.: 2

Procedures:

1. Inspect exterior of equipment for damage or missing hardware.

2. Inspect the power cord, strain relief and plug/s for any signs of damage.

3. Turn unit off, open user-accessible covers and inspect unit for damage.

4. Clean unit interior components and exterior with vacuum or compressed air.

5. Inspect interior for signs of corrosion or missing hardware. Repair as required.

6. Inspect electrical components for signs of excessive heat or deterioration.

7. Perform battery operation test.

8. Test instrument service/test mode.

9. Verify pressure calibration.

10. Perform auto pinch-off test.

11. Verify rate accuracy.

12. Verify correct operation of all buttons, controls, displays and/or indicators.

13. Verify correct operation of unit in all functional modalities.

overview Appendix B 6

X-ray system, mobile

FDA risk: 11

Safety insp./Yr.: 1

Programme risk score:

Perf. insp./Yr.: 2

Risk group: Diagnostic

PM checks/Yr.: 2

Procedures:

1. Inspect exterior of equipment for damage or missing hardware.

2. Inspect the power cord, strain relief and plug/s for any signs of damage.

3. Turn unit off, open user-accessible covers and inspect unit for damage.

4. Clean unit interior components and exterior with vacuum or compressed air.

5. Inspect interior for signs of corrosion or missing hardware. Repair as required.

6. Inspect electrical components for signs of excessive heat or deterioration.

7. Verify accuracy of kVp, mA-time, per manufacturer's specifications.

8. Verify correct operation of electrical locks (tube and table).

9. Verify correct operation of other electrical functions.

10. Inspect batteries if applicable; service as required.

11. Verify correct support and travel of stationary and movable rails.

12. Verify smooth operation of the drive system.

13. Verify correct operation of display devices if applicable.

14. Verify correct operation within specifications of collimators (auto and manual).

15. Verify correct calibration using manufacturer's specifications.

16. Verify correct operation of all buttons, controls, displays and/or indicators.

17. Verify correct operation of unit in all functional modalities.

18. Clean exterior of unit including all accessories, cables, controls and displays.

Appendix C

Calculating IPM workload

The following procedure and charts are used to calculate IPM workload. This mathematical methodology is used by service companies to calculate the PM workload of the accounts they bid on. If the clinical engineering department calculates the actual work needed to accomplish this task and acquires the staff to do this work, the more likely the work will be accomplished and the goals achieved. The steps are as follows: 1. Identify the areas to be covered for IPM (a group of equipment, a department, a new wing, a whole facility).

2. Create a complete inventory of each item to be covered for IPM.

3. Record time it takes a technician to perform the inspection procedure. Each piece of equipment should be analysed, the inspection frequency and times entered into a spreadsheet and the total annual time for inspection and preventive maintenance calculated for the list of equipment to be covered. An example of this is provided in Chart A.

Chart A: Calculating IPM workload, detailed method Minor IPM

Major IPM

frequency

Minor IPM time frequency

Major IPM time Total time

Medical Equipment

(per year)

(hours)

(per year)

(hours)

(hours/year)

Laboratory chemistry department

Laboratory blood refrigerator

11

0.2

1

0.5

0.7

Laboratory specimen refrigerator

1

0.5

1

0.5

1

Heating block

2

0.25

0

0

0.5

Spectrophotometer

3

0.5

1

0.75

2.25

Bilirubin analyzer

2

0.75

1

1.0

2.5

Chemistry analyzer

3

3.0

1

4.0

13.0

Printer module

2

0.3

0

0

0.6

Computer printer

2

0.3

0

0

0.6

Computer monitor

1

0.25

0

0.25

Chemistry analyzer

3

4.5

1

6.0

19.5

Microscope

1

0.5

1

1.5

2.0

Laboratory freezer

1

0.3

1

0.5

0.8

Laboratory mixer

2

0.25

0

0

0.5

Centrifuge

2

0.5

1

1.0

2.0

Chemistry analyzer

3

3.0

1

5.0

14.0

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Medical equipment maintenance programme overview Refrigerator

1

0.3

1

0.4

0.7

Chemistry analyzer

3

3.0

1

4.0

13.0

Water purification system

1

1.0

1

2.0

3.0

Total

76.9 hrs.

Labour and delivery department

Fetal monitor

4

0.75

0

0

3.0

Ultrasound scanner

1

3.0

1

5.0

8.0

Video monitor

1

0.5

0

0

0.5

Infant radiant warmer

2

0.75

1

1.0

2.5

Infant radiant warmer

2

0.75

1

1.0

2.5

Pulse oximeter

1

0.3

1

0.4

0.7

Warming blanket

1

0.5

1

1.0

1.5

Fetal monitor

4

0.75

0

0

3.0

Physiological monitor

1

0.75

1

1.0

1.75

Doppler blood flow probe

2

0.3

0

0

0.6

Syringe pump

1

0.5

1

0.75

1.25

Electrosurgical unit

1

1.0

1

1.0

2.0

Fetal monitor

4

0.75

0

0

3.0

Fetal blood gas monitor

2

1.5

1

2.0

5.0

Fetal monitor

4

0.75

0

0

3.0

Fetal blood gas monitor

2

1.5

1

2.0

5.0

Total

43.3 hrs.

An alternate, simplified method to do this is to generally categorize each device into one of three classifications:

1. Simple device – inspected once per year with no PM required; 2. Intermediate devices – inspected once or twice per year, some PM may be required; 3. Advanced systems – inspected 2–4 times per year, extensive PM required.

This method requires some familiarity with the equipment and maintenance procedures.

The approximate inspection times and frequencies for each class of equipment is entered into the chart and the calculations are done to yield the total IPM work time.

An example of this method is found in Chart B.

Chart B: Determining workload

(This example uses the chemistry and delivery room inventory above) Equipment type

Simple devices

Intermediate devices

Advanced systems

Number of devices

5 Chemistry

8 Chemistry

4 Chemistry

1 Delivery

14 Delivery

3 Delivery

Total number of devices

6.0

22.0

7.0

Hours/inspection

0.3

0.5

1.0

Inspections/year

1.0

1.5

4.0

Total hours inspecting equipment

1.8

16.5

28.0

Total Workload = 46.3

This method yields the total time needed to provide complete inspection and preventive maintenance on this inventory. This example did not take into account the time needed to travel to the clinical site to perform the work, the time to get ready for work in a particular area (gather correct paperwork, test equipment, tools and PM parts) or the time it takes to complete the paperwork after the work is done. These tasks are variable depending where the department is located with respect to the clinical areas, where the work takes place and what type of equipment will be maintained. Additionally time should be taken out of the normal work day for lunch, short breaks and short conversations with the clinical staff to build rapport and to learn about how the equipment has been functioning. All things considered, this example yields about two weeks of work for a single technician to accomplish this work in a careful and thorough manner.

Examples of inventory and inspection forms

D.1 New equipment form

D.2 Equipment inspection form

D.3 Work order form

Appendix D 1

New equipment received form

Date:

Tech Name:

Equipment

Category

Floor Unit

Dept.

Details

Purchase Info

Note:

Arrival Date

/ /

Asset #

Installation Date

/ /

Model #

Warranty Date

/ /

Serial #

Purchase Price

$

Vendor #

Replacement Cost

$

Manufacturer

Functional Units

Life Expectancy yrs

Function Score

Risk Score

PM Schedule

(monthly, annual, etc.)

Maintenance Score

Work Order #

Purchase PO

Incoming #

Comments

72

Medical equipment maintenance programme overview

7.4 INSPECTION FORM

Medi-Therm III Hyper/Hypothermia
Functional Check / Inspection Form *

Location _____ Serial number _____

Item				OK? (Y/N)	Action needed	Action Taken (Date / Initials)
a. Condition of chassis						
b. Condition of attachment plug						
c. Line cord and strain reliefs						
d. Circuit breaker						
e. Condition of lights and alarm						
f. Flow		MTA6900	MTA6901			
	1. Greater than . . . [HEATING]	16 GPH (60.6 l/hr)	12 GPH (45.4 l/hr)			
	2. Greater than . . . [COOLING]	16 GPH (60.6 l/hr)	12 GPH (45.4 l/hr)			
	3. Flow switch activation					
g. Level switch activation						
h. Cold water reservoir controller: 37.4°F (3°C) to 42.8°F (6°C)						
i. Blanket water temperature controller and display test:						
	Temperature Control Setpoint	Display Reading	Mercury Thermometer Reading			
	50°F (10°C)					
	77°F (25°C)					
	105.8°F (41°C)					
Display readings within 1.8°F (1°C) of temperature setpoint Mercury thermometer reading within 1.8°F (1°C) of temperature setpoint						
j.	S2: High temperature backup thermostat: 111.2°F (44°C) to 120.2°F (49°C)					
	S3: High temperature backup thermostat: 111.2°F (44°C) to 120.2°F (49°C)					
k. Thermostat verification test: S2/S3						
l. Patient temperature display test:						
	Probe Resistance (ohms)	Patient Temperature Display				
	1355	98.6°F ± 0.5°F (37°C ± 0.3°C)				
	1667	89.6°F ± 0.5°F (32°C ± 0.3°C)				
m. Low temperature backup thermostat (S1): 26.6°F (-3.0°C) to 36.5°F (+2.5°C)						
n. Ground resistance less than 0.5 ohms						
o. Current leakage:						
	Chassis (grounded)	10 microamps max.				
	Chassis (ungrounded)	100 microamps max.				
	Patient Probe	50 microamps max.				
p. Reset of RFU code						

* Complete entire Functional Check / Inspection Form prior to troubleshooting unit.

Appendix D 2

Equipment inspection forms

WHO Medical device technical series

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Quality Assurance Program Form 200-0498
Ventilator Service Report

MEDIQ/PRN LIFE SUPPORT SERVICES, INC. (800)-257-7477 or (800)-232-6960

THIS FORM WILL BE SCANNED. PLEASE WRITE INSIDE BOXES. USE CAPITAL LETTERS.

Date M M D D Y Y Type: ☐ SPI ☐ PM ☐ Repair ☐ Recall TB #_____ ☐ Warranty Repair ☐ Other_____ MEDIQ/PRN BARCODE ☐ NEW

Branch ID Employee ID Work Order Customer # RA #

Device Type _____ SPI/PM Rev. No. _____
Manufacturer _____
Model _____ Mfr S/N _____
Hours _____ Previous SPI/PM Date _____

☐ CUST. OWNED EQUIPMENT CUST. EQP. ID _____
CUSTOMER NAME _____
LOCATION _____

ITEM	PASS	N/A	QUALITATIVE TASKS
1.1			Chassis / Housing
1.2			Mount / Fasteners
1.3			Casters / Brakes
1.4			AC Plug / Receptacles
1.5			Line Cord
1.6			Strain Reliefs
1.7			Circuit Breaker / Fuse
1.8			Tubes / Hoses
1.9			Cables
1.10			Fittings / Connectors
1.11			Electrodes / Transducers
1.12			Filters
1.13			Controls / Switches
1.14			Heater / Humidifier
1.15			Motor / Pump / Fan / Compressor
1.16			Fluid Levels
1.17			Battery / Charger
1.18			Indicators / Displays
1.19			User Cal / Self Test
1.20			Alarms / Interlocks
1.21			Audible Signals
1.22			Labeling
1.23			Accessories
1.24			
2.1			Ground Resistance_____ Ω
2.2			Max. Leakage Current_____ μA
2.3			Leak Test
2.4			Control Mode
2.5			Assist Control Mode
2.6			SIMV Mode
2.7			CPAP Mode
2.8			Pressure Support Mode
2.9			Nebulizer Function
2.10			Rates (CMV/SIMV)

ENTER TEST VALUES	Set	Displayed	Measured
→			
→			

2.11			Rates (SIGH)
2.12			SIGH Function

ITEM	PASS	N/A	QUANTITATIVE TASKS
2.13			Volumes

2.14 ENTER TEST VALUES	Set	Displayed	Measured
→			
→			

2.15			Pressure Limits

ENTER TEST VALUES	Set	Displayed	Measured
→			
→			

2.16			Oxygen Percentage

ENTER TEST VALUES	Set	Displayed	Measured
→			
→			

2.17			Relief Valve
2.18			Sensitivity
2.19			Apnea Alarm
2.20			Low Oxygen Pressure Alarm
2.21			Low Inspiratory Pressure Alarm
2.22			Low Exhale/Minute Volume Alarm
2.23			Low PEEP/CPAP Alarm
2.24			High Rate Alarm
2.25			Temperature Alarm
2.26			High Oxygen % Alarm

ITEM	PASS	N/A	QUANTITATIVE TASKS
2.27			Low Oxygen % Alarm
2.28			Fail-to-cycle/Vent INOP Alarm
2.29			I:E Ratio
2.30			Low Air Pressure Alarm
2.31			
2.32			
2.33			
2.34			
2.35			
2.36			

ITEM	PASS	N/A	ADDITIONAL TASKS
3.1			Clean
3.2			Lubricate
3.3			Calibrate
3.3a			Calibrate Regulators
3.3b			Calibrate Switches
3.3c			Calibrate Transducers
3.3d			Calibrate Compressor Output
3.4			Replace
3.4a			Replace Air/O2 Filters
3.4b			Replace Compressor Filters
3.5			Battery: ☐ tested ☐ replaced

REMARKS/COMMENTS

RECORD REASON FOR SERVICE AND DESCRIBE CORRECTIVE ACTION TAKEN

PARTS AND ACCESSORIES

QTY	TELSTAR ID	LOT/SERIAL NUMBER	DESCRIPTION		

S ☐ N ☐

FAIL ← CHECK ONE & SIGN BELOW → PASS

EMPLOYEE SIGNATURE

© 1998 COPYRIGHT MEDIQ/PRN - YOUR ONE SOURCE RENTAL CO.

Note: This form is to be retained in the active file until 12 days after final repairs have been completed.

REQUEST FOR SERVICE

Department: _____ Division: _____

Date: _____

Technologist Reporting Problem: _____

Room Number of Model Number: _____

Describe Problem: _____

_____

_____

Call Placed By: _____ Date\Time: _____

(To Be Completed By Service Engineer)

SERVICE RECORD

SE Name: _____ Date\Time Responded: _____

Action Taken: _____

_____

Has the problem been corrected? _____

Is further follow-up work necessary? _____ (If so, describe on reverse side of this form.)

FOLLOW-UP ACTION

SE Name: _____ Date\Time Responded: _____

Action Taken: _____

_____

Has the problem been corrected? _____

Is follow-up work necessary? _____

When will follow-up work be performed? _____

Appendix D 3

Work order form

WHO Medical device technical series

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Appendix E

Samples of inspection labels

E.1 Record of inspection

E.2 Record of inspection (test) results

E.3 Notification on defect warning label

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Medical equipment maintenance programme overview

HARTFORD HOSPITAL
BIOMEDICAL ENGINEERING

☐ PREVENTATIVE MAINTENANCE BY: _____
☐ ELECTRICAL SAFETY DATE: _____
☐ OPERATIONAL CHECK DUE: (date/hrs) _____

HARTFORD HOSPITAL
BIOMEDICAL ENGINEERING

☐ PREVENTATIVE MAINTENANCE BY: _____
☐ ELECTRICAL SAFETY DATE: _____
☐ OPERATIONAL CHECK DUE: (date/hrs) _____

HARTFORD HOSPITAL
BIOMEDICAL ENGINEERING

☐ PREVENTATIVE MAINTENANCE BY: _____
☐ ELECTRICAL SAFETY DATE: _____
☐ OPERATIONAL CHECK DUE: (date/hrs) _____

HARTFORD HOSPITAL
BIOMEDICAL ENGINEERING

☐ PREVENTATIVE MAINTENANCE BY: _____
☐ ELECTRICAL SAFETY DATE: _____
☐ OPERATIONAL CHECK DUE: (date/hrs) _____

ATTENTION

THIS UNIT MUST
STAY PLUGGED IN
TO MAINTAIN BATTERY

UAL BE307

BATTERY

Dates
☐ Checked _____
☐ Replaced _____
By _____

DEFIBRILLATOR CALIBRATION

INDICATED	DELIVERED
WS	WS
WS	WS
WS	WS
WS	WS
WS	WS
MAX.	

DATE _____ BY _____
NEXT INSPECTION DUE _____

BIOMEDICAL ENGINEERING DEPT.
SAFETY CHECKED
By _____
Date _____
UAL BE290

ELECTRICAL SAFETY CHECK
NON-HOSPITAL OWNED DEVICE
☐ RENTAL ☐ LOANER ☐ EVAL. ☐ OTHER
BY _____ DATE _____
Next Inspection Due _____

Defective
DO NOT USE
REPAIR _____
INSPECTED BY____ DATE ____

DEFECTIVE
DO NOT USE
Comments: _____
_____
_____
_____
_____
DATE: _____ BY: _____
BE437

REMOVED FROM SERVICE

_____ _____
DATE INITIALS

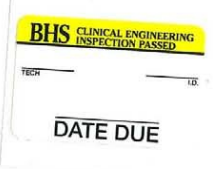
MUST RECEIVE PM/ELECTRICAL
SAFETY INSPECTION PRIOR TO
RETURNING TO SERVICE

SERVICED
Date _____ by
Due _____
Service Performed
CAL PM PT ST
DO NOT REMOVE LABEL
BE737
SERVICED
Date _____ by
Due _____
Service Performed
CAL PM PT ST
DO NOT REMOVE LABEL
BE737

ST. FRANCIS HOSPITAL
Clinical Engineering Ex 44225
INSPECTED
DATE
BY
DUE

DUE
DATE
INSPECTED
BY
ST. FRANCIS HOSPITAL
Clinical Engineering Ex 44225

BHS CLINICAL ENGINEERING INSPECTION PASSED
TECH
I.D.
DATE DUE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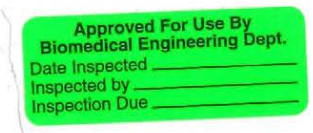
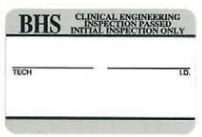
TECH
I.D.
DATE DUE


Approved For Use By
Biomedical Engineering Dept.
Date Inspected
Inspected by
Inspection Due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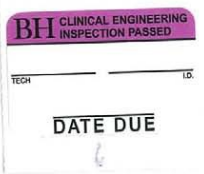
I.D.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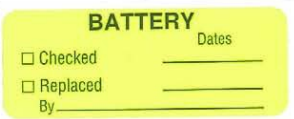
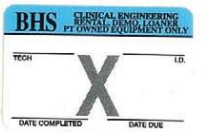

BATTERY
Dates
☐ Checked
☐ Replaced
By

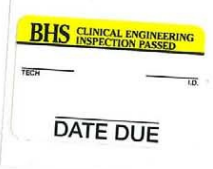

BHS CLINICAL ENGINEERING RENTAL DEMO LOANER PT OWNED EQUIPMENT ONLY
TECH
I.D.
X
DATE COMPLETED
DATE DUE

SERVICED
Date _____ by
Due _____
Service Performed
CAL PM PT ST
DO NOT REMOVE LABEL
BE737
SERVICED
Date _____ by
Due _____
Service Performed
CAL PM PT ST
DO NOT REMOVE LABEL
BE737

ST. FRANCIS HOSPITAL
Clinical Engineering Ex 44225
INSPECTED
DATE
BY
DUE

DUE
DATE
INSPECTED
BY
ST. FRANCIS HOSPITAL
Clinical Engineering Ex 44225

BHS CLINICAL ENGINEERING INSPECTION PASSED
TECH
I.D.
DATE DUE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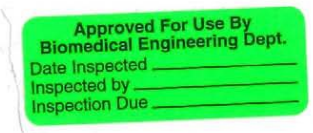
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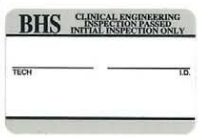
Date Inspected
Inspected by
Inspection Due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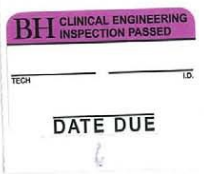
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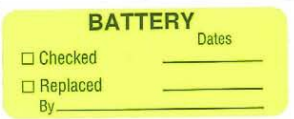
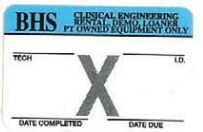
DATE DUE


BATTERY
Dates
☐ Checked
☐ Replaced
By

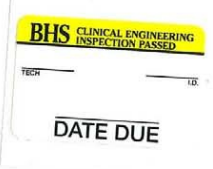

BHS CLINICAL ENGINEERING RENTAL DEMO LOANER PT OWNED EQUIPMENT ONLY
TECH
I.D.
X
DATE COMPLETED
DATE DUE

SERVICED
Date _____ by
Due _____
Service Performed
CAL PM PT ST
DO NOT REMOVE LABEL
BE737
SERVICED
Date _____ by
Due _____
Service Performed
CAL PM PT ST
DO NOT REMOVE LABEL
BE737

ST. FRANCIS HOSPITAL
Clinical Engineering Ex 44225
INSPECTED
DATE
BY
DUE

DUE
DATE
INSPECTED
BY
ST. FRANCIS HOSPITAL
Clinical Engineering Ex 44225

BHS CLINICAL ENGINEERING INSPECTION PASSED
TECH
I.D.
DATE DUE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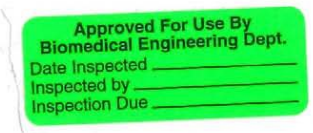
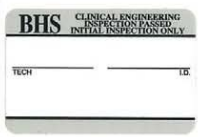

Approved For Use By
Biomedical Engineering Dept.
Date Inspected
Inspected by
Inspection Due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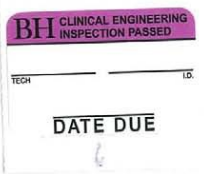
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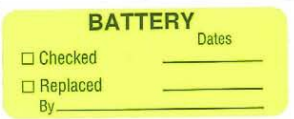
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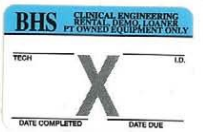
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BE737

ST. FRANCIS HOSPITAL
Clinical Engineering Ex 44225
INSPECTED
DATE
BY
DUE

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ST. FRANCIS HOSPITAL
Clinical Engineering Ex 44225

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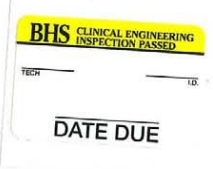
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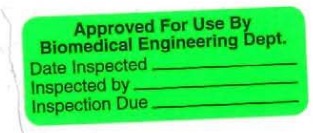
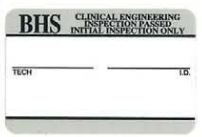

Approved For Use By
Biomedical Engineering Dept.
Date Inspected
Inspected by
Inspection Due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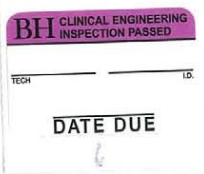
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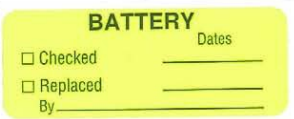
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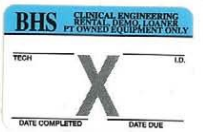
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DATE COMPLETED
DATE DUE

HARTFORD HOSPITAL
BIOMEDICAL ENGINEERING

☐ PREVENTATIVE MAINTENANCE BY: _____
☐ ELECTRICAL SAFETY DATE: _____
☐ OPERATIONAL CHECK DUE: (date/hrs) _____

HARTFORD HOSPITAL
BIOMEDICAL ENGINEERING

☐ PREVENTATIVE MAINTENANCE BY: _____
☐ ELECTRICAL SAFETY DATE: _____
☐ OPERATIONAL CHECK DUE: (date/hrs) _____

HARTFORD HOSPITAL
BIOMEDICAL ENGINEERING

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HARTFORD HOSPITAL
BIOMEDICAL ENGINEERING

☐ PREVENTATIVE MAINTENANCE BY: _____
☐ ELECTRICAL SAFETY DATE: _____
☐ OPERATIONAL CHECK DUE: (date/hrs) _____

ATTENTION

THIS UNIT MUST
STAY PLUGGED IN
TO MAINTAIN BATTERY

UAL BE307

BATTERY

Dates
☐ Checked _____
☐ Replaced _____
By _____

DEFIBRILLATOR CALIBRATION

INDICATED	DELIVERED
WS	WS
WS	WS
WS	WS
WS	WS
WS	WS
MAX.	

DATE _____ BY _____
NEXT INSPECTION DUE _____

BIOMEDICAL ENGINEERING DEPT.
SAFETY CHECKED
By _____
Date _____
UAL BE290

ELECTRICAL SAFETY CHECK
NON-HOSPITAL OWNED DEVICE
☐ RENTAL ☐ LOANER ☐ EVAL. ☐ OTHER
BY _____ DATE _____
Next Inspection Due _____

Defective
DO NOT USE
REPAIR _____
INSPECTED BY____ DATE ____

DEFECTIVE
DO NOT USE
Comments: _____
_____
_____
_____
_____
DATE: _____ BY: _____
BE437

REMOVED FROM SERVICE

_____ _____
DATE INITIALS

MUST RECEIVE PM/ELECTRICAL
SAFETY INSPECTION PRIOR TO
RETURNING TO SERVICE

HARTFORD HOSPITAL
BIOMEDICAL ENGINEERING

☐ PREVENTATIVE MAINTENANCE BY: _____
☐ ELECTRICAL SAFETY DATE: _____
☐ OPERATIONAL CHECK DUE: (date/hrs) _____

HARTFORD HOSPITAL
BIOMEDICAL ENGINEERING

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HARTFORD HOSPITAL
BIOMEDICAL ENGINEERING

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HARTFORD HOSPITAL
BIOMEDICAL ENGINEERING

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☐ OPERATIONAL CHECK DUE: (date/hrs) _____

ATTENTION

THIS UNIT MUST
STAY PLUGGED IN
TO MAINTAIN BATTERY

UAL BE307

BATTERY

Dates
☐ Checked _____
☐ Replaced _____
By _____

DEFIBRILLATOR CALIBRATION

INDICATED	DELIVERED
WS	WS
WS	WS
WS	WS
WS	WS
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MAX.	

DATE _____ BY _____
NEXT INSPECTION DUE _____

BIOMEDICAL ENGINEERING DEPT.
SAFETY CHECKED
By _____
Date _____
UAL BE290

ELECTRICAL SAFETY CHECK
NON-HOSPITAL OWNED DEVICE
☐ RENTAL ☐ LOANER ☐ EVAL. ☐ OTHER
BY _____ DATE _____
Next Inspection Due _____

Defective
DO NOT USE
REPAIR _____
INSPECTED BY____ DATE ____

DEFECTIVE
DO NOT USE
Comments: _____
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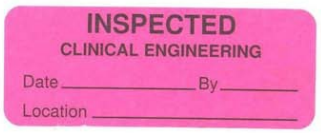
DATE: _____ BY: _____
BE437

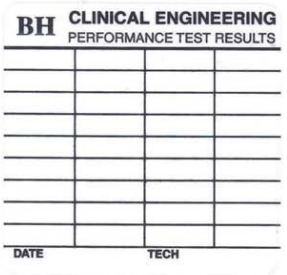
REMOVED FROM SERVICE

_____ _____
DATE INITIALS

MUST RECEIVE PM/ELECTRICAL
SAFETY INSPECTION PRIOR TO
RETURNING TO SERVICE



Simple paper" inspection completed" sticker indicating the date inspected and owner department. These tags are sometimes printed in different colors, one for each year or inspection cycle. Then it is easier to identify which devices are now due for inspection. This tag may be covered with a plastic adhesive cover to protect it from being defaced during the cleaning process.



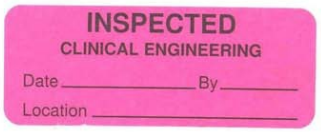
A paper calibration tag which provides space to record the output readings taken during the performance assurance inspection. These can be used to record outputs on many energy producing devices including ultrasound therapy equipment, lasers, defibrillators, electro-current therapy devices, nerve stimulators, etc.

This label is placed on medical equipment which has been inspected by the clinical engineering staff and found to be defective. It is printed on a very brightly colored paper to attract the clinician's visual attention and prevent inadvertent use of the device.

Appendix E 1

Record of inspection labels

A sticker indicating the date inspected and owner department. These tags are sometimes printed in different colours, one for each year or inspection cycle. Then it is easier to identify devices that are due for inspection. This tag may be covered with plastic adhesive/cover to protect it from being defaced during the cleaning process.



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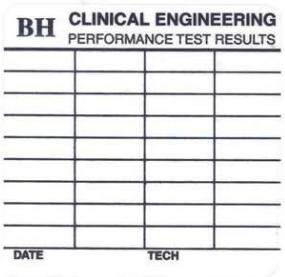

A paper calibration tag which provides space to record the output readings taken during the performance assurance inspection. These can be used to record outputs on many energy producing devices including ultrasound therapy equipment, lasers, defibrillators, electro-current therapy devices, nerve stimulators, etc.

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ULTRASOUND OUTPUT

ID NO. _____ DATE _____

TESTED BY _____

ULTRASOUND SETTING (WATTS)	ACTUAL OUTPUT (WATTS)

UAL BE425

ST. FRANCIS HOSPITAL
Clinical Engineering Ex. 44225

NON-HOSPITAL OWNED

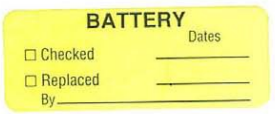
PERFORMANCE CHECK ☐ ☐ BME 08
ELECTRICAL SAFETY CHECK ☐

DATE _____ BY _____

☐ RENTAL ☐ LEASED ☐ LOANER

☐ DEMO ☐ P. OWNED ☐ OTHER

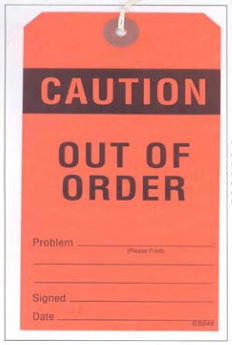
VOID IF REMOVED FROM HOSPITAL



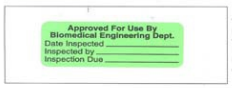
Appendix E 2

Record of inspection (test) results

A paper calibration tag provides space to record the output readings taken during the performance assurance inspection. These can be used to record outputs on many energy-producing devices including ultrasound therapy equipment, lasers, defibril ators, electrocurrent therapy devices, nerve stimulators, etc.

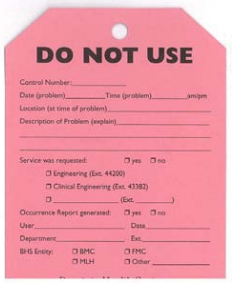


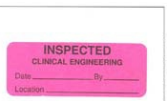
This brightly colored paper tag is for use by the clinical staff to identify equipment which is reported to clinical engineering as needing repair. It uses a string to attach to the defective equipment so the equipment is not damaged by adhesive placed in the wrong location.



This inspection sticker is used to identify patient or physician owned equipment which is temporarily brought into the hospital for use by its owner. It indicates that the device was inspected and was found to be safe and operational.

Other example labels are shown on the next page.





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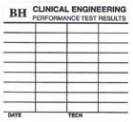

A paper calibration tag which provides space to record the output readings taken during the performance assurance inspection. These can be used to record outputs on many energy producing devices including ultrasound therapy equipment, lasers, defibrillators, electro-current therapy devices, nerve stimulators, etc.

This label is placed on medical equipment which has been inspected by the clinical engineering staff and found to be defective. It is printed on a very brightly colored paper to attract the clinician's visual attention and prevent inadvertent use of the device.

Appendix E 3

Notification on defect warning label

This label is placed on medical equipment that has been inspected by the clinical engineering staff and found to be defective. It is printed on very brightly coloured paper to attract the clinician's visual attention and prevent inadvertent use of the device.

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Appendix F

Test equipment per medical device category

Medical device category	Test equipment required
Electrosurgical units	Radio frequency electrosurgical analyzer
Defibrillators	Defibrillator analyzer
All electrical equipment	Electrical safety analyzer
Anaesthesia machines, ventilators	Test lung
Anaesthesia machines, ventilators	Ventilation analyzer
Heart lung machines, hyper/hypothermia machines, warming Fluid flow meter pad pumps, dialysis machines	Anaesthesia machines, ventilators, CO insufflators, vacuum Gas flow meters
2	regulators, air-O blenders, lasers
2	Physiological monitors, intra-aortic balloon pumps, Physiological simulators
defibrillators, EEG machines, EKG machines	ICU monitors, EKG machines
Arrhythmia simulators	IV pump, surgical irrigation pump
Graduated cylinder	Radiographic and fluoroscopic equipment
Ionization chamber/radiation analyzer/kVp meter	Surgical and ophthalmic lasers
Laser power meter/laser thermal imaging plates	Most electronic equipment
Multimeter/oscilloscope/function generator	Radiographic, mammography, ultrasound, CT, MR
Phantoms	Air-O blenders, anesthesia machines, medical gas systems Oxygen analyzer
2	Pacemakers
Pacemaker analyzer	Scales, traction units
Scales, spring scale, floor scale, balance, weights Ventilators, heart-lung machine, anaesthesia machine Pneumatic tester, pneumatic flow meter	Medical gas systems, insufflators, lasers, haemodialysis Pressure meter
machines, suction regulators	Incubators, infant warmers, laboratory ovens
Temperature probe/thermometers	Infusion pumps, traction units
Stop watch/timers	Centrifuges
Photo or contact tachometer	Electrical outlets
Receptacle testers	

Isolated power systems

Isolated power tester

Non-invasive blood pressure monitors

Non-invasive blood pressure simulator

Dialysis machine

pH/conductivity meter

Various

Variable resistance box, variable capacitance box

Examples of job descriptions

G.1 Biomedical equipment technician – entry-level G.2 Biomedical equipment technician – mid-level G.3 Biomedical equipment technician – senior-level G.4 Clinical engineering supervisor/manager

WHO Medical device technical series

Biomedical equipment technician – entry-level

Job description:

Performs tasks involving the installation and maintenance of therapeutic, diagnostic and monitoring medical equipment.

These activities include:

1. Installation, maintenance and repair of a diverse range of medical equipment.

2. Performing electrical safety inspections on medical equipment using specialized test equipment.

3. Assisting in the systematic preventive maintenance programme of medical equipment.

4. Documenting al work performed including new equipment inspections, corrective and preventive maintenance and special requests as required. Maintaining documentation in an accurate and timely manner.

5. Assisting hospital clinical and technical staff in the proper operation and maintenance of clinical equipment.

6. Communication with users regarding status of repairs. Meeting the needs of clinical departments and obtaining loaner or replacement equipment as required.

7. Acceptance testing on new clinical equipment per department policy.

8. Being aware of patient- and work-safety issues, reports problems found and assists with correction of issues as required.

9. Identifying and recommending medical equipment that is obsolete, has an extensive repair history, no longer has service support from the manufacturer or has identified safety problems.

10. Providing good customer service, answering phones in a pleasant manner, screening and referring calls as appropriate and providing information to staff, visitors and patients, upon request.

11. Maintaining a professional appearance and approach to work.

12. Maintaining good relationships with fel ow workers, clinical staff and other hospital workers.

13. Maintaining a high level of productivity. Making suggestions to improve department productivity when appropriate.

14. Maintaining a clean and safe work place.

15. Following all departmental policies and procedures.

Education: Two-year degree or equivalent training in electronics, biomedical equipment technology or a related field is required.

Experience: No experience required above minimum education. One-year experience as a biomedical equipment technician in a health-care setting preferred.

Biomedical equipment technician – mid-level

Job description:

Performs tasks involving the installation and maintenance of therapeutic, diagnostic and monitoring medical equipment.

These activities include:

1. Performance of both routine and complex tasks associated with the installation, maintenance, and repair of a diverse range of clinical equipment including life support equipment.

2. Working independently in both routine and complex tasks. Being able to prioritize work and initiate new work and tasks.

3. Being able to effectively work with clinicians to troubleshoot clinical problems with medical equipment. Being able to solve technology problems for the clinicians.

4. Providing training, mentoring and guidance for entry level technicians.

5. Participation in committees as requested.

6. Coordination of initial inspection and instal ation of new equipment as requested.

7. Coordination and management of projects from start to completion, performing any necessary communication and follow-up with owner department.

8. Assisting with pre-purchase evaluations of equipment as required. Participation in incident investigations as requested and provides follow-up to management.

Education: Two-year degree or equivalent training in electronics, biomedical equipment technology or a related field is required.

Experience: At least three years experience as a biomedical equipment technician or a minimum of five years experience in electronic, mechanical or electromechanical repair or equivalent, preferably in a healthcare setting.

Appendix G 3

Biomedical equipment technician – senior-level

Job description:

Performs tasks involving the installation and maintenance of therapeutic, diagnostic and monitoring medical equipment.

These activities include:

1. Being able to consistently perform a wide variety of routine, complex and specialized tasks associated with the installation, maintenance and repair of a wide range of clinical equipment including life support equipment.

2. Training, mentoring and guidance to entry-level and mid-level technicians 3. Conducting training sessions for department staff covering safe operation and maintenance of equipment for entry and mid-level technicians.

4. Assisting in developing technical specifications for equipment purchases.

5. Routinely coordinating and managing projects, performing any necessary communication and follow-up with department.

6. Leadership and prioritization of work in the absence of the manager.

Education: Two-year degree or equivalent training in electronics, biomedical equipment technology or a related field is required.

Experience: Requires a minimum of four years experience as a biomedical equipment technician.

 Appendix G 4

Clinical engineering supervisor/manager

Job description:

Performs tasks involving the installation and maintenance of therapeutic, diagnostic and monitoring medical equipment.

These activities include:

1. Acquisition, maintenance and repair of the medical equipment.

2. Assisting and overseeing writing specifications for new equipment.

3. Evaluation and assistance in acquiring new technology for patient care.

4. Coordination of preventive maintenance and repairs of outside service personnel.

5. Evaluation of possible service contracts and outside vendor relationships.

6. Maintaining familiarity with regulatory codes and standards.

7. Collaboration with clinical staff to provide the highest level of patient safety.

8. Ensuring that applicable accreditation standards are met.

9. Ensuring departmental policies and procedures are followed.

10. Managing other projects as assigned.

11. Managing department productivity and performance improvement initiatives.

12. Assistance in the management of the computerized maintenance management system.

13. Ensuring the timely completion and documentation of al maintenance activities.

14. Maintaining the stock of repair parts to ensure appropriate maintenance of equipment.

15. Ensuring timely completion of preventive maintenance.

16. Representing clinical engineering at meetings as assigned.

17. Instructing hospital personnel on safe and proper operation and maintenance of medical equipment.

Education: Requires a two-year degree in clinical/biomedical engineering or equivalent.

A four-year degree in clinical/biomedical engineering is preferred.

Experience: Work requires minimum of three years of clinical/biomedical technology experience including management and leadership experience.

WHO Medical device technical series

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Appendix H

Case Studies

H.1 Small hospital planning example

H.2 Small hospital management example

H.3 Regional health system planning example

H.4 Regional health system management example 86

Medical equipment maintenance programme overview Appendix H 1

Small hospital planning example

A small hospital has:

• one technician with limited training;

• one room with limited equipment;

• a very limited budget.

To make its maintenance activities as focused and effective as possible, it needs the following:

Critical factor

Action

Responsible party

Inventory

Create an inventory of all medical equipment in the hospital Clinical engineering department using a computer spreadsheet or simple CMMS software.

Methodology

• Identify current resources

Clinical engineering department

• Define maintenance methodologies:

manager

simple maintenance tasks - hospital staff,

critical equipment of greater complexity - service contracts Financial resources

Plan for service contracts.

Clinical engineering department

• Develop the budget for implementing the programme.

manager

• Develop the budget for operating the programme.

• Identify budget sources.

Physical resources

Plan for build-out of space and acquisition of tools and Architect

equipment.

Plan for basic computer resources.

Administrator

Human resources

• Plan additional training for technician.

Clinical engineering department

• Identify managerial capabilities within the hospital for manager / administrator

management of the programme.

• Develop links to external resources.

Appendix H 2

Small hospital management example

Management

Action

Responsible party

component

Personnel

• Assigns scheduled and unscheduled work to the repair Clinical engineering department

management

person.

manager

• Monitor hours worked by the technician and timely completion of scheduled and unscheduled work

assignments.

Document work on work order forms and, if available, in the Technician CMMS software.

Financial

• Monitor costs associated with service contracts and with Clinical engineering department management

work carried out by the technician.

manager

• Compare costs to budget, review variances, plan for future budgets.

Operational

• Develop procedures and schedules for inspection and Clinical engineering department

management

preventive maintenance.

manager

• Develop policies for prioritizing corrective maintenance activities.

• Monitor services provided under service contracts.

Work closely with clinicians.

Clinical engineering department

manager / technician

Performance

Monitor only those performance measures described above. Clinical engineering department monitoring

manager

Performance

Compare performance to objectives annually; identify Clinical engineering department

improvement

opportunities for improvement.

manager

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Medical equipment maintenance programme overview Appendix H 3

Regional health system planning example

Critical factor

Action

Responsible person

Inventory

Create inventory of all medical equipment in the system Clinical engineering department

using full-featured CMMS software.

Methodology

Define maintenance methodologies:

Clinical engineering department

simple and moderate maintenance tasks - hospital staff manager

critical equipment of greater complexity - service contracts, with “first look” by hospital staff

Financial resources

• Identify financial resources (moderate).

Clinical engineering department

• Plan for service contracts.

manager

• Develop budget for implementing the programme.

• Develop budget for operating the programme.

• Identify budget sources.

Physical resources

Identify physical resources (some space, tools, and Clinical engineering department

equipment).

manager

Plan for build-out of space and acquisition of tools and Architect

equipment.

Plan for basic computer resources.

Administrator

Plan for transportation among hospitals and clinics.

Administrator / transport services

officer

Plan for service request dispatching and clerical support.

Administrator

Human resources

Identify current human resources (one engineer and a few Clinical engineering department

technicians with varying skills).

manager

• Plan additional general and specialised training for Clinical engineering department

technicians.

manager / administrator

• Plan management training for the engineer.

• Develop links to external resources.

WHO Medical device technical series

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Appendix H 4

Regional health system management example

Management

Action

Responsible person

component

Personnel

• CMMS assigns scheduled and unscheduled work using Clinical engineering department

management

defined protocols.

manager

• Monitor hours worked by the technical staff and timely completion of scheduled and unscheduled work assignments.

Technical personnel document work on work order forms Technician

and in the CMMS software.

Financial

Monitor costs associated with service contracts and with work Clinical engineering department management

carried out by technical staff.

manager

Operational

• Develop procedures and schedules for inspection and Clinical engineering department

management

preventive maintenance.

manager

• Work closely with clinicians and conduct customer satisfaction surveys.

• Develop policies for prioritizing corrective maintenance activities.

• Monitor services provided under service contracts.

• Participate in medical equipment planning, incident investigation and committee activities.

Work closely with clinicians and conduct customer satisfaction Clinical engineering department surveys.

manager

/ technician

Performance

• Monitor performance measures described above plus Clinical engineering department

monitoring

additional measures supported by the CMMS.

manager

• Manage compliance with applicable standards,

performance benchmarking, and implementation of

“best practices.”

Performance

• Prepare written report comparing performance

Clinical engineering department

improvement

to objectives and identifying opportunities for

manager

improvement.

• Implement performance improvement initiatives and monitor for success.

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